

FDA U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

FDA Industry Systems

SYSTEM

HELP DESK

STATUS

LOGIN

Existing account holders, enter your account ID & password.
Account ID:

Password:

Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

I Understand

[Forgot your password?](#)

NEW USER

>

> Create New Account

>

>

> See Instructions

>

>

> See Tutorials

>

>

> Help Desk

GETTING STARTED

To make submissions to FDA (e.g., Food Facility Registration, Prior Notice, etc.) you must first create an account. Select "Create New Account" below.

If you already have an account, enter your **account ID** and **password**.

WARNING: You are accessing a U.S. Government information system. The system usage may be monitored, recorded, and subject to audit. Unauthorized use of the system is prohibited and subject to criminal and civil penalties. Use of the system indicates consent to monitoring and recording, and Anyone using this system expressly consents to such monitoring and is advised that if such monitoring reveals possible criminal activity, system personnel may provide the evidence of such monitoring to law enforcement officials.

Is your computer secure? Before using FDA Industry Systems (FIS), FDA strongly encourages all users to have current antivirus and antispyware software installed on your computer to help ensure the privacy of the information being entered.

FDA retains contractors to assist the agency in maintaining its databases. If you get a call from someone asking about your facility and you are concerned about whether the call is legitimate, get the name and company of the caller, as well as a phone number, and contact **FDA FURLS Helpdesk at 1-800-216-7331** to confirm that the caller is acting on behalf of FDA.

Account Management

Account Management
Edit Account Profile
Change My Password
Update System Access
Create a Subaccount
Deactivate a Subaccount
Reactivate a Subaccount

WELCOME You are logged in as **gns21746**

Welcome to the FDA Industry Systems.

You are logged in to your account for company **gnsi**

You may choose an option on the left to manage your account or select an FDA system below. To obtain access to available FDA systems, choose the Update System Access option to add the FDA system to your account.

FDA UNIFIED REGISTRATION LISTING SYSTEMS

- [▶ Food Facility Registration](#)
- [▶ Device Registration & Listing](#)
- [▶ Shell Egg Registration](#)
- [▶ Drug Facility Registration](#)
- [▶ Acidified/Low Acid Canned Foods](#)
- [▶ Certificate Application Process](#)
- [▶ CDRH Export Certificate Application & Tracking System](#)

OTHER FDA SYSTEMS

- [▶ Prior Notice of Imported Food](#)



CECATS MAIN MENU

Enter New Application

Form Approval: OMB No.0910-0498

Expiration date:3/31/2015
See OMB Statement at end of form

Modify Application

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Search Application

Please Note:

The system will automatically time out if there is no activity for 30 minutes and you will need to re-do your work from the beginning.




[Get Help](#) 

Please select the certificate type you are applying for. If you are unsure as to which one to select, please click on the "ICON" for a description of each certificate type.

*** - These fields are required**

Certificate Type :

Certificate to Foreign Government (CFG) 

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[Continue](#)



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Save & Exit

Continue to Step 2

Cancel & Start Again

SECTION 1 REQUESTOR INFORMATION

If the information below is incorrect, you will need to update your account before proceeding any further . Click on [here](#) to navigate to the Online Account Administration to make the necessary updates.

*** - These fields are required**

*Salutation

Mr.

*First Name

Middle Initial

*Last Name

*Title

*Firm

*Country / Area

UNITED STATES

*Address Line 1

Address Line 2

*Zip Code (Postal Code)

* City

*State / Province / Territory

Numbers only. No spaces, dashes or parentheses. Country Code is not required for U.S. phone numbers.

Country Code	Area / City Code	*Phone Number	Extension
(e.g.001)	(e.g.101)	(e.g.5551111)	(e.g.1111)

*Phone Number

Country Code	Area / City Code	Fax Number
(e.g.001)	(e.g.101)	(e.g.5551111)

Fax Number

*Firm Tax ID Code

-

*Email Address

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STEP1 ADDRESS VALIDATION

This address has been verified; however minor modifications were made to the information you entered. Please indicate whether you wish to accept the modifications we made, or Click on FURLS Home to navigate to the Online Account Administration to make the necessary updates.

YOUR ADDRESS

REQUESTOR FIRM NAME: gnsi

REQUESTOR FIRST NAME: Vijay

REQUESTOR LAST NAME: Maringanti

STREET ADDRESS, Line 1: 11820 Parklawn DR**STREET ADDRESS, Line 2:** 300**CITY:** Rockville**STATE:** Maryland**ZIP/POSTAL CODE:** 20852**COUNTRY:** UNITED STATES

VALIDATED ADDRESS

REQUESTOR FIRM NAME: gnsi

REQUESTOR FIRST NAME: Vijay

REQUESTOR LAST NAME: Maringanti

STREET ADDRESS, Line 1: 11820 Parklawn Dr Ste 300**STREET ADDRESS, Line 2:****CITY:** Rockville**STATE:** Maryland**ZIP/POSTAL CODE:** 20852-2529**COUNTRY:** UNITED STATES

Accept validated address and continue



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[Back to Step 1](#)[Cancel & Start Again](#)**SECTION 2 MANUFACTURER INFORMATION**

The FDA requires that all facilities manufacturing medical devices must be registered in the FDA Device Registration and Listing Facility(DRLM) system. Once a manufacturer is registered in the DRLM, the FDA provides an Owner Operator Number to the requesting firm. The FDA also assigns a Registration number for every manufacturer registered in DRLM. If you have not registered your manufacturer in DRLM, click on [here](#) to navigate to DRLM and register your manufacturer. Otherwise, please enter the Registration Number or the Owner Operator Number.

* - These fields are required

*Registration Number :

OR

*Owner Operator Number :

[Retrieve Registrations](#)[Back to Step 1](#)[Cancel & Start Again](#)



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SECTION 2 MANUFACTURER INFORMATION

Please select a manufacturer(s) and click add.

NOTE: Only a manufacturer in an "Active" or "Active Pending Registration Number" status in DRLM can be selected.

Firm	Registration Number	Status	Address (P.O. Box not acceptable)
GNSI - Class I Exempt Only With Inspection		Active	311 W Side Dr Apt 301 , Gaithersburg , Maryland UNITED STATES , 20878
GNSI - Class I Exempt Only With No Inspection		Active	11820 Parklawn Dr Ste 300 , Rockville , Maryland UNITED STATES , 20852

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Add



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SECTION 2 MANUFACTURER INFORMATION

The following manufacturer(s) has been added to the certificate request.

Firm	Registration Number	Status	Address (P.O. Box not acceptable)
GNSI - Class I Exempt Only With Inspection		Active	311 W Side Dr Apt 301 , Gaithersburg, Maryland UNITED STATES , 20878

Do you want to add another manufacturer? Yes No

Continue



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[Back to Step 1](#)[Review Manufacturer List](#)[Cancel & Start Again](#)**SECTION 2 MANUFACTURER INFORMATION**

The FDA requires that all facilities manufacturing medical devices must be registered in the FDA Device Registration and Listing Facility(DRLM) system. Once a manufacturer is registered in the DRLM, the FDA provides an Owner Operator Number to the requesting firm. The FDA also assigns a Registration number for every manufacturer registered in DRLM. If you have not registered your manufacturer in DRLM, click on [here](#) to navigate to DRLM and register your manufacturer. Otherwise, please enter the Registration Number or the Owner Operator Number.

* - These fields are required

*Registration Number :

OR

*Owner Operator Number :

[Retrieve Registrations](#)[Back to Step 1](#)[Review Manufacturer List](#)[Cancel & Start Again](#)



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SECTION 2 MANUFACTURER INFORMATION

Please select a manufacturer(s) and click add.

NOTE: Only a manufacturer in an "Active" or "Active Pending Registration Number" status in DRLM can be selected.

Firm	Registration Number	Status	Address (P.O. Box not acceptable)
RICK'S MEDICAL DEVICE FIRM(510k)	786898	Active	11820 Parklawn Dr Ste 300 , Rockville , Maryland UNITED STATES , 20852

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Add



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SECTION 2 MANUFACTURER INFORMATION

The following manufacturer(s) has been added to the certificate request.

Firm	Registration Number	Status	Address (P.O. Box not acceptable)
RICK'S MEDICAL DEVICE FIRM(510k)	786898	Active	11820 Parklawn Dr Ste 300 , Rockville, Maryland UNITED STATES , 20852

Do you want to add another manufacturer? Yes No

Continue



Get Help

Continue

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SECTION 2 MANUFACTURER INFORMATION

*** - These fields are required**

Firm Name

Registration Number

Address Line 1

Address Line 2

City

State / Province / Territory

*Country / Area

Zip Code (Postal code)

License Number (if applicable)

Date of Last FDA inspection (MM/DD/YYYY)

Continue

Cancel & Start Again



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SECTION 2 MANUFACTURER INFORMATION

The following manufacturer(s) has been added to the certificate request.
 You may optionally enter the Date of Last FDA Inspection by selecting the manufacturer and clicking on "Edit".

You can add an additional manufacturer by clicking on "Add".

You can remove an existing manufacturer by selecting a manufacturer and clicking on "Remove".

Firm	Registration Number	License number (if applicable)	Date of Last FDA Inspection	Address (P.O. Box not acceptable)
GNSI - Class I Exempt Only With Inspection			03/01/2011	311 W Side Dr Apt 301, Gaithersburg, Maryland UNITED STATES , 20878
RICK'S MEDICAL DEVICE FIRM(510k)	786898			11820 Parklawn Dr Ste 300, Rockville, Maryland UNITED STATES , 20852



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[Back to Step 2](#)[Continue to Step 4](#)[Cancel & Start Again](#)**SECTION 3 DISTRIBUTOR INFORMATION (IF APPLICABLE)**

The FDA requires that all facilities manufacturing medical devices must be registered in the FDA Device Registration and Listing Facility(DRLM) system. Once a distributor is registered in the DRLM, the FDA provides an Owner Operator Number to the requesting firm. The FDA also assigns a Registration number for every distributor registered in DRLM.If you have not registered your distributor in DRLM, click on [here](#) to navigate to DRLM and register your distributor. Otherwise, please enter the Registration Number or the Owner Operator Number.

* - These fields are required

*Registration Number :

OR

*Owner Operator Number :

[Retrieve Registrations](#)[Back to Step 2](#)[Continue to Step 4](#)[Cancel & Start Again](#)



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SECTION 3 DISTRIBUTOR INFORMATION (IF APPLICABLE)

Please select a distributor(s) and click add.

NOTE: Only a domestic distributor in an "Active" or "Active Pending Registration Number" status in DRLM can be selected.

Firm	Registration Number	Status	Address (P.O. Box not acceptable)
RICK'S MEDICAL DEVICE FIRM(510k)	786898	Active	11820 Parklawn Dr Ste 300 , Rockville , Maryland UNITED STATES , 20852

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Add



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SECTION 3 DISTRIBUTOR INFORMATION (IF APPLICABLE)

The following distributor(s) has been added to the certificate request.

Firm	Registration Number	Status	Address (P.O. Box not acceptable)
RICK'S MEDICAL DEVICE FIRM(510k)	786898	Active	11820 Parklawn Dr Ste 300 , , Rockville, Maryland, UNITED STATES , 20852

Do you want to add more distributor's? Yes No

Continue



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SECTION 3 DISTRIBUTOR INFORMATION (IF APPLICABLE)

The following distributor(s) has been added to the certificate request.

Select	Firm	Registration Number	Address (P.O. Box not acceptable)
	RICK'S MEDICAL DEVICE FIRM(510k)	786898	11820 Parklawn Dr Ste 300 , Rockville , Maryland UNITED STATES , 20852



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SECTION 4 PRODUCT INFORMATION

Warning: You may list Class III products only if the manufacturing facility has been inspected by the FDA. Failure to comply will prompt the FDA to immediately reject the certificate request.

*Will you be listing any refurbished or remanufactured products in this application? Yes No

*Are you the original manufacturer of this product(s)? Yes No

Please be advised that any refurbished or remanufactured product cannot appear on the certificate unless you are the original manufacturer.

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Cancel & Start Again



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Cancel & Start Again

SECTION 4 PRODUCT INFORMATION

In this section you will be able to retrieve all products associated to a facility registered in DRLM. Please select a facility and click on "Add/Remove Product"

NOTE: You must select at least one product for each facility listed below in order to continue.

Select	Manufacturer	Product Details
<input type="checkbox"/>	GNSI - Class I Exempt Only With Inspection	
<input type="checkbox"/>	RICK'S MEDICAL DEVICE FIRM(510k) 786898	

Select	Distributor	Product Details
<input type="checkbox"/>	RICK'S MEDICAL DEVICE FIRM(510k) 786898	

Add/Remove Product

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SECTION 4 PRODUCT INFORMATION

Please select the product(s) for this facility. You may optionally enter the Trade Name and or Proper Name for each product selected.

If you wish to have the Proper Name printed on the certificate, you will need to enter the Proper Name for each product.

NOTE: Only the Proper Name can be printed on the certificate.

	Marketing Status	Product Code	Product Name	Trade Name	Proper Name
	Exempt	JCF	LYMPHOCYTE SEPARATION MEDIUM		
	Exempt	GIF	DILUENT, BLOOD CELL		



Get Help

SECTION 4 PRODUCT INFORMATION

Please select the product(s) for this facility. You may optionally enter the Trade Name and or Proper Name for each product selected.

If you wish to have the Proper Name printed on the certificate, you will need to enter the Proper Name for each product.

NOTE: Only the Proper Name can be printed on the certificate.

	Marketing Status	Product Code	Product Name	Trade Name	Proper Name
	Exempt	JCF	LYMPHOCYTE SEPARATION MEDIUM		
	Exempt	GIF	DILUENT, BLOOD CELL		



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Cancel & Start Again

SECTION 4 PRODUCT INFORMATION

In this section you will be able to retrieve all products associated to a facility registered in DRLM. Please select a facility and click on "Add/Remove Product"

NOTE: You must select at least one product for each facility listed below in order to continue.

Select	Manufacturer	Product Details		
		Trade Name	Proper Name	Marketing Status
	GNSI - Class I Exempt Only With Inspection	tn1	pn1	Exempt
	RICK'S MEDICAL DEVICE FIRM(510k) 786898			

Select	Distributor	Product Details		
	RICK'S MEDICAL DEVICE FIRM(510k) 786898			

Add/Remove Product

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SECTION 4 PRODUCT INFORMATION

Please select the product(s) for this facility. You may optionally enter the Trade Name and or Proper Name for each product selected.

If you wish to have the Proper Name printed on the certificate, you will need to enter the Proper Name for each product.

NOTE: Only the Proper Name can be printed on the certificate.

Marketing Status	Product Code	Product Name	Trade Name	Proper Name
K991735	DPS	ELECTROCARDIOGR APH		
	DQK	COMPUTER, DIAGNOSTIC, PROGRAMMABLE		
	DXH	TRANSMITTERS AND RECEIVERS, ELECTROCARDIOGR APH, TELEPHONE		
	LOS	System, ecg analysis		
K974749	KWP	APPLIANCE, FIXATION, SPINAL INTERLAMINAL		
	KWQ	APPLIANCE, FIXATION, SPINAL INTERVERTEBRAL BODY		
	MNH	Orthosis, spondylolisthesis spinal fixation		
K992748	DIO	ENZYME IMMUNOASSAY, COCAINE AND COCAINE METABOLITES		
	DKZ	ENZYME IMMUNOASSAY, AMPHETAMINE		
	DPK	LIQUID CHROMATOGRAPHY, MORPHINE		
	LCM	Enzyme immunoassay, phencyclidine		
		ENZYME		

LDJ

IMMUNOASSAY,
CANNABINOIDS

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SECTION 4 PRODUCT INFORMATION

In this section you will be able to retrieve all products associated to a facility registered in DRLM. Please select a facility and click on "Add/Remove Product"

NOTE: You must select at least one product for each facility listed below in order to continue.

Select	Manufacturer	Product Details		
	GNSI - Class I Exempt Only With Inspection	Trade Name tn1	Proper Name pn1	Marketing Status Exempt
	RICK'S MEDICAL DEVICE FIRM(510k) 786898	Trade Name	Proper Name	Marketing Status
		Trade Name2	Proper Name2	K991735
		Trade Name3	Proper Name3	K974749

Select	Distributor	Product Details		
	RICK'S MEDICAL DEVICE FIRM(510k) 786898			



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SECTION 5 WAS THE PRODUCT EVER RECALLED ?

If any product listed below has ever been recalled, please place a checkmark next to the product and enter the FDA Issued Recall Number.

Once completed, click on "Continue"

Recalled	Firm	Marketing Status	Product Code	Product Name
	GNSI - Class I Exempt Only With Inspection	Exempt	JCF	LYMPHOCYTE SEPARATION MEDIUM
	FDA Issued Recall Number : Z-		-	Close-out Date (MM/DD/YYYY) :
	RICK'S MEDICAL DEVICE FIRM(510k)	K991735	DPS	ELECTROCARDIOGRAPH
			DQK	COMPUTER, DIAGNOSTIC, PROGRAMMABLE
			DXH	TRANSMITTERS AND RECEIVERS, ELECTROCARDIOGRAPH, TELEPHONE
			LOS	System, ecg analysis
	FDA Issued Recall Number : Z-		-	Close-out Date (MM/DD/YYYY) :
	RICK'S MEDICAL DEVICE FIRM(510k)	K974749	KWP	APPLIANCE, FIXATION, SPINAL INTERLAMINAL
			KWQ	APPLIANCE, FIXATION, SPINAL INTERVERTEBRAL BODY
			MNH	Orthosis, spondylolisthesis spinal fixation
	FDA Issued Recall Number : Z-		-	Close-out Date (MM/DD/YYYY) :



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SECTION 5 WAS THE PRODUCT EVER RECALLED ?

Our records indicate that the product(s) listed below does not have a recall close-out date. If available, please upload the official Close-Out Letter for each recalled product. Failure to do so may cause a delay in the certificate processing.

NOTE: The Close-Out Letter attachment cannot exceed 50MB (Megabytes).
 The total file size of all Close-Out Letter attachments cannot exceed 50MB (Megabytes).
 The accepted file formats include pdf, bmp, jpeg, gif, png, tiff, doc, and docx.

Firm	Product Code	Product Name	FDA Issued Recall Number	Close-out-Letter
GNSI - Class I Exempt Only With Inspection	JCF	LYMPHOCYTE SEPARATION MEDIUM	Z-1039-05	no file selected <input type="button" value="Upload"/>



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SECTION 6 LIST COUNTRY(IES) FOR WHICH THE CERTIFICATES ARE REQUESTED

*NAME OF COUNTRY or COUNTRIES

AFGHANISTAN
ALAND ISLANDS
ALBANIA
ALGERIA
AMERICAN SAMOA
ANDORRA

>> Add
>> Remove

AFGHANISTAN
ALAND ISLANDS

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Back to Step 6 Save & Exit Continue
Cancel & Start Again

SECTION 7 INDICATE WHAT PRODUCT INFORMATION SHOULD
APPEAR ON THE CERTIFICATE

***Please select primary facility :** GNSI - Class I Exempt Only With Inspection - Manufacturer

*Do you want to display the owner operator address for the primary facility selected on the certificate ? Yes No

Back to Step 6 Save & Exit Continue
Cancel & Start Again



Get Help

SECTION 7 INDICATE WHAT PRODUCT INFORMATION SHOULD APPEAR ON THE CERTIFICATE

Select the facilities and Header / Sub header names that you wish to appear on the certificate :

Select	Manufacturer	Header Name	SubHeader Name
	GNSI - Class I Exempt Only With Inspection	Name of Manufacturer/Distributor	Manufacturing Facility
	RICK'S MEDICAL DEVICE FIRM(510k)	Name of Owner Operator	Formerly Known As
Formerly Known As :			

Select	Distributor	Header Name	SubHeader Name
	RICK'S MEDICAL DEVICE FIRM(510k)	Name of Distributor	Manufactured For
Manufactured For :			



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SECTION 7 INDICATE WHAT PRODUCT INFORMATION SHOULD
APPEAR ON THE CERTIFICATE

NOTE: If you have not entered all of the Proper Names for each product in section 4, please go back and enter the information, or you will not be able to select "Use the existing product listing (from section 4) to appear on the certificate?"

Use the existing product listing (from section 4) to appear on the certificate?

OR

Upload your product accessories?

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Restart Step 7

SECTION 7 INDICATE WHAT PRODUCT INFORMATION SHOULD APPEAR ON THE CERTIFICATE

This section allows you to associate each product or product listing to one or more facilities that have been identified to be printed on the certificate. The associations you create will impact the printout of your certificate.

Select one or multiple products from each page. Then select one or more facilities. When you are finished, click on "Group". Continue grouping the remaining products until all products from the first page has been grouped. Click on the "Next" hyperlink to continue to the next set of products (if available).

NOTE: You must associate each product to at least one facility. If there are multiple pages of products, you must associate the products for each page before continuing to the next page of products.

Refer to the online help for more detailed instructions on product groupings and an example of a certificate printout.

Products	Owner Operator/Manufacturer(s)/Distributor(s)
pn1	Manufacturer(s)
Proper Name2	GNSI - Class I Exempt Only With Inspection
Proper Name3	RICK'S MEDICAL DEVICE FIRM(510k)-786898
	Distributor(s)
	RICK'S MEDICAL DEVICE FIRM(510k)-786898

Clear Group

Group

Clear All Groupings

Group All Products to All Facilities

Restart Step 7

Review Product Groupings



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SECTION 7 INDICATE WHAT PRODUCT INFORMATION SHOULD
APPEAR ON THE CERTIFICATE

NOTE: If you have not entered all of the Proper Names for each product in section 4, please go back and enter the information, or you will not be able to select "Use the existing product listing (from section 4) to appear on the certificate?"

Use the existing product listing (from section 4) to appear on the certificate?

OR

Upload your product accessories?

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SECTION 7 INDICATE WHAT PRODUCT INFORMATION SHOULD
APPEAR ON THE CERTIFICATE

The maximum allowed file size is 50 MB (Megabytes). The accepted file types are Microsoft 2007 or 2010 Excel Spreadsheets (.xls or .xlsx). Click [here](#) to download the product template file.

Select the file to upload:

no file selected

Upload

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Restart Step 7

SECTION 7 INDICATE WHAT PRODUCT INFORMATION SHOULD
APPEAR ON THE CERTIFICATE

This section allows you to associate each product or product listing to one or more facilities that have been identified to be printed on the certificate. The associations you create will impact the printout of your certificate.

Select one or multiple products from each page. Then select one or more facilities. When you are finished, click on "Group". Continue grouping the remaining products until all products from the first page has been grouped. Click on the "Next" hyperlink to continue to the next set of products (if available).

NOTE: You must associate each product to at least one facility. If there are multiple pages of products, you must associate the products for each page before continuing to the next page of products.

Refer to the online help for more detailed instructions on product groupings and an example of a certificate printout.

>> Next

Products	Owner Operator/Manufacturer(s)/Distributor(s)
Extracting forceps , American Pattern , Fig A 151 S Pillers , Endo notched Locking Needle holders, CRILE-WOOD , 15cm Needle holders, DERF , 12.5cm Needle holders, MAYO-HEGAR , 16cm Rubberdam punch , IVORY Rubberdam punch , AINSWORTH Rubberdam clamp forceps ; BREWER Hemostatic forceps , KELLY , 14cm Hemostatic forceps , KELLY , 14cm , Curved Cheek retractors , CAEWOOD-MINNESOTA , 16cm Crown Scissors , BEEBEE , 10.5 cm Gum Scissors , LA-GRANGE , 11,5 cm , Sharp-Sharp , S-shape. Root Elevators , FLOHR L Root Elevators , CRYER L Raspatories , FREER , 18.5 cm C.S. Mirror #4 C.S. Mirror #4 12 pack C.S. Mirror #5 C.S. Mirror #5 12 Pack Gracey Deep Pocket 1-2 xp 3/8" Resin Gracey Deep Pocket 1-2 xp 3/8" Stainless Gracey Deep Pocket 3-4 xp 3/8" Resin Gracey Deep Pocket 3-4 xp 3/8" Stainless Cassette SL5 (5 Instr) Cassette SL5 (7 Instr - no rack) Cassette 108(8 Instr)	RICK'S MEDICAL DEVICE FIRM(510k)- 786898(Manufacturer)

Cassette 108 utility (8 Instr)
 Cassette 108 Removable Rack(8-16 Instr)
 Cassette 109 W/12 Slots

Products	Owner Operator/Manufacturer(s)/Distributor(s)
Extracting forceps , American Pattern , Fig A 151 S	Manufacturer(s)
Pillars , Endo notched Locking	RICK'S MEDICAL DEVICE FIRM(510k)-786898
Needle holders, CRILE-WOOD , 15cm	
Needle holders, DERF , 12.5cm	Distributor(s)
Needle holders, MAYO-HEGAR , 16cm	RICK'S MEDICAL DEVICE FIRM(510k)-786898
Rubberdam punch , IVORY	
Rubberdam punch , AINSWORTH	
Rubberdam clamp forceps ; BREWER	
Hemostatic forceps , KELLY , 14cm	
Hemostatic forceps , KELLY , 14cm , Curved	
Cheek retractors , CAEWOOD-MINNESOTA , 16cm	
Crown Scissors , BEEBEE , 10.5 cm	
Gum Scissors , LA-GRANGE , 11,5 cm , Sharp-Sharp , S-shape.	
Root Elevators , FLOHR L	
Root Elevators , CRYER L	
Raspatories , FREER , 18.5 cm	
C.S. Mirror #4	
C.S. Mirror #4 12 pack	
C.S. Mirror #5	
C.S. Mirror #5 12 Pack	
Gracey Deep Pocket 1-2 xp 3/8" Resin	
Gracey Deep Pocket 1-2 xp 3/8" Stainless	
Gracey Deep Pocket 3-4 xp 3/8" Resin	
Gracey Deep Pocket 3-4 xp 3/8" Stainless	
Cassette SL5 (5 Instr)	
Cassette SL5 (7 Instr - no rack)	
Cassette 108(8 Instr)	
Cassette 108 utility (8 Instr)	
Cassette 108 Removable Rack(8-16 Instr)	
Cassette 109 W/12 Slots	



Get Help

Restart Step 7

SECTION 7 INDICATE WHAT PRODUCT INFORMATION SHOULD APPEAR ON THE CERTIFICATE

This section allows you to associate each product or product listing to one or more facilities that have been identified to be printed on the certificate. The associations you create will impact the printout of your certificate.

Select one or multiple products from each page. Then select one or more facilities. When you are finished, click on "Group". Continue grouping the remaining products until all products from the first page has been grouped. Click on the "Next" hyperlink to continue to the next set of products (if available).

NOTE: You must associate each product to at least one facility. If there are multiple pages of products, you must associate the products for each page before continuing to the next page of products.

Refer to the online help for more detailed instructions on product groupings and an example of a certificate printout.

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Products	Owner Operator/Manufacturer(s)/Distributor(s)
Probe 1 Yellow 7/32" stainless	Manufacturer(s) RICK'S MEDICAL DEVICE FIRM(510k)-786898
Probe 1 Yellow 3/8 " Resin	
Probe 12 Yellow 7/32 " Resin	Distributor(s) RICK'S MEDICAL DEVICE FIRM(510k)-786898
Probe 12 Yellow 7/32 " Stainless	
Explorer 23 (SE) 3/8" Resin	
Explorer 2 (DE) 3/8" Resin	
Explorer 3 (SE) 7/32" Stainless	
Curette Columbia 12-14 xp 3/8" Resin	
Curette Columbia 12-14 xp 3/8" Stainless	
Curette Columbia 12-14 xp 7/32" Resin	
Waxing PKT 1 1/4" Stainless	

<< Previous

Clear Group

Group

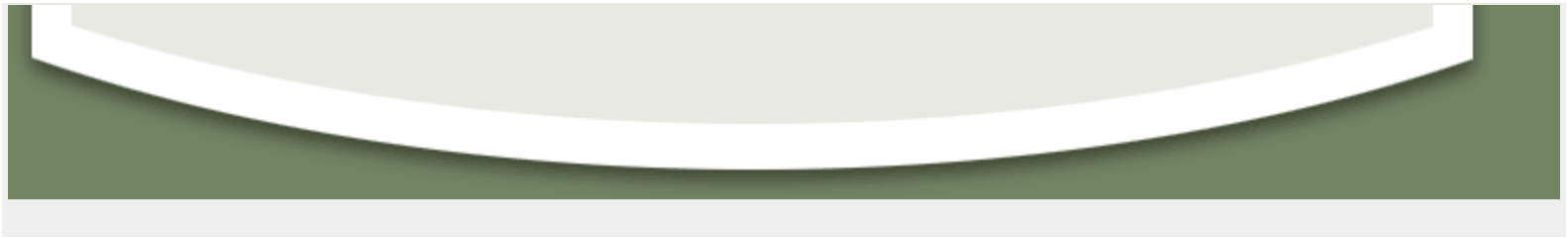
Clear All Groupings

Group All Products to All Facilities

Reupload Products

Restart Step 7

Review Product Groupings





Get Help

Back to Step 6

Save & Exit

Continue to Step 8

Cancel & Start Again

SECTION 7 INDICATE WHAT PRODUCT INFORMATION SHOULD APPEAR ON THE CERTIFICATE

Products	Owner Operator/Manufacturer(s)/Distributor(s)
Extracting forceps , American Pattern , Fig A 151 S Pillers , Endo notched Locking Needle holders, CRILE-WOOD , 15cm Needle holders, DERF , 12.5cm Needle holders, MAYO-HEGAR , 16cm Rubberdam punch , IVORY Rubberdam punch , AINSWORTH Rubberdam clamp forceps ; BREWER Hemostatic forceps , KELLY , 14cm Hemostatic forceps , KELLY , 14cm , Curved Cheek retractors , CAEWOOD-MINNESOTA , 16cm Crown Scissors , BEEBEE , 10.5 cm Gum Scissors , LA-GRANGE , 11,5 cm , Sharp-Sharp , S-shape. Root Elevators , FLOHR L Root Elevators , CRYER L Raspatories , FREER , 18.5 cm C.S. Mirror #4 C.S. Mirror #4 12 pack C.S. Mirror #5 C.S. Mirror #5 12 Pack Gracey Deep Pocket 1-2 xp 3/8" Resin Gracey Deep Pocket 1-2 xp 3/8" Stainless Gracey Deep Pocket 3-4 xp 3/8" Resin Gracey Deep Pocket 3-4 xp 3/8" Stainless Cassette SL5 (5 Instr) Cassette SL5 (7 Instr - no rack) Cassette 108(8 Instr) Cassette 108 utility (8 Instr) Cassette 108 Removable Rack(8-16 Instr) Cassette 109 W/12 Slots	RICK'S MEDICAL DEVICE FIRM(510k)-786898(Manufacturer)
Probe 1 Yellow 7/32" stainless Probe 1 Yellow 3/8 " Resin Probe 12 Yellow 7/32 " Resin Probe 12 Yellow 7/32 " Stainless Explorer 23 (SE) 3/8" Resin Explorer 2 (DE) 3/8" Resin Explorer 3 (SE) 7/32" Stainless Curette Columbia 12-14 xp 3/8" Resin Curette Columbia 12-14 xp 3/8" Stainless Curette Columbia 12-14 xp 7/32" Resin	RICK'S MEDICAL DEVICE FIRM(510k)-786898(Manufacturer) RICK'S MEDICAL DEVICE FIRM(510k)-786898(Distributor)

Waxing PKT 1 1/4" Stainless

Back to Step 6

Save & Exit

Continue to Step 8

Cancel & Start Again



Get Help

[Back to Step 7](#) [Save & Exit](#) [Continue to Step 9](#)

[Cancel & Start Again](#)

SECTION 8 SHOULD THE COUNTRY DESTINATION BE LISTED ON THE CERTIFICATE?

(Note : CDRH does not list a specific country on a certificate.)

Should the country destination be listed on the certificate ? Yes No

Indicate the total number of certificates requested :

[Back to Step 7](#) [Save & Exit](#) [Continue to Step 9](#)

[Cancel & Start Again](#)



Step 01

Step 02

Step 03

Step 04

Step 05

Step 06

Step 07

Step 08

Step 09



Get Help

Back to Step 8

Save & Exit

Continue

Cancel & Start Again

SECTION 9 EXPORTER'S CERTIFICATION STATEMENT

Department of Health and Human Services Food and Drug Administration	EXPORTER'S CERTIFICATION STATEMENT "CERTIFICATE TO FOREIGN GOVERNMENT " for CDRH
---	---

Primary Facility : RICK'S MEDICAL DEVICE FIRM(510k) - Manufacturer

As a responsible official or designee authorized to represent and act on behalf of the facility named immediately above, I hereby certify to the Food and Drug Administration (FDA) that the facility(s) and the products identified on the Supplemental Information are to the best of my knowledge in substantial compliance with the Federal Food, Drug, and Cosmetic Act (the Act) and all applicable or pertinent regulations including the following:

1. All Facilities that appear on the certificate are currently registered and each facility has listed each of its medical devices identified for export as required by Section 510 of the Act and 21 CFR Part 807 (See attached Supplementary Information Page);
2. Each product(s) identified for export is legally marketed within the United States and is the subject of a 510(k) premarket notification or is a device that was in commercial distribution before May 28, 1976, or exempt, or is the subject of a premarket approval application;
3. Each product(s) identified is not subject of an open recall or the subject of any current enforcement action initiated by FDA ; and
4. All manufacturers, contract manufacturers, and contract sterilizers involved in the manufacturing process have been identified on the 3613 form.
5. The requesting facility and all facilities involved in the manufacturing process are operating in substantial compliance with the Good Manufacturing Practices Regulation (21 CFR Part 820) for the identified product(s).
6. There are no HIV products listed on the certificate.
7. Each product(s) identified for export is being exported from the United States.

I hereby make this certification of compliance statement to FDA with full knowledge that the making or submission of false statements represents violations of United State Code Title 18, Chapter 47, Section 1001. Penalties include up to \$250,000 in fines and up to five years of imprisonment.

*I Agree

Date :

*Name :

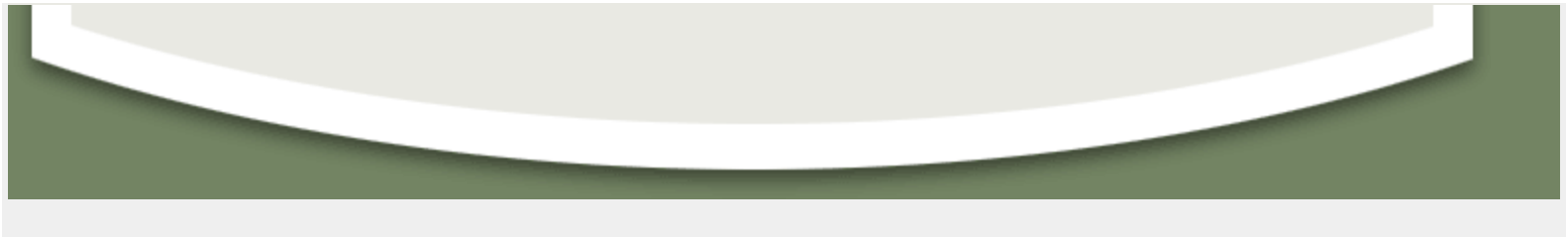
*Title :

Back to Step 8

Save & Exit

Continue

Cancel & Start Again





Get Help

SECTION 9 EXPORTER'S CERTIFICATION STATEMENT

Each facility intended to be printed on the certificate must have a corresponding Exporter's Certification Statement (ECS). Please upload the ECS to the corresponding facility. You will not be able to submit the application without the ECS for each facility.

If you do not have the ECS, click on the "Save & Exit" button and return to the application when you have the necessary documentation.

NOTE: The ECS attachment cannot exceed 50MB (Megabytes).
 The total file size of all ECS attachments cannot exceed 50MB (Megabytes).
 The accepted file formats include pdf, bmp, jpeg, gif, png, tiff, doc, and docx.

Name of the Distributor(s)	
*RICK'S MEDICAL DEVICE FIRM(510k)	no file selected <input type="button" value="Upload"/>



Step 01

Step 02

Step 03

Step 04

Step 05

Step 06

Step 07

Step 08

Step 09



Get Help

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Save & Exit

Continue

Cancel & Start Again

SECTION 9 EXPORTER'S CERTIFICATION STATEMENT

Each facility intended to be printed on the certificate must have a corresponding Exporter's Certification Statement (ECS). Please upload the ECS to the corresponding facility. You will not be able to submit the application without the ECS for each facility.

If you do not have the ECS, click on the "Save & Exit" button and return to the application when you have the necessary documentation.

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The total file size of all ECS attachments cannot exceed 50MB (Megabytes).
The accepted file formats include pdf, bmp, jpeg, gif, png, tiff, doc, and docx.

Name of the Distributor(s)		
*RICK'S MEDICAL DEVICE FIRM(510k)	1346441380299_162-8-2012_cert.pdf	Remove

Back

Save & Exit

Continue

Cancel & Start Again


[Get Help ?](#)

Please review your application. If all information is correct, click the **Submit** button below. To make changes to a section, click the **Edit** button for that section.

Date: 08/31/2012

Created Date: 08/31/2012

Certificate Type: Certificate to Foreign Government (CFG)

SECTION 1 REQUESTOR INFORMATION EDIT

Name :Mr. Vijay Maringanti		Address : 11820 Parklawn Dr Ste 300 , Rockville , Maryland UNITED STATES , 20852	
Firm : gnsi			
Telephone number : 301-4656565	FAX Number :	Firm Tax ID code : 12 - 1211111	Email address : vijayasarathi.maringanti@fda.hhs.gov

SECTION 2 MANUFACTURER INFORMATION EDIT

Firm : GNSI - Class I Exempt Only With Inspection	Address (P.O. Box not acceptable): 311 W Side Dr Apt 301 , Gaithersburg , Maryland UNITED STATES , 20878
Registration number :	
License number :	Date of Last FDA inspection : 03/01/2011
⌆	
Firm : RICK'S MEDICAL DEVICE FIRM(510k)	Address (P.O. Box not acceptable) : 11820 Parklawn Dr Ste 300 , Rockville , Maryland UNITED STATES , 20852
Registration number : 786898	
License number (if applicable) :	Date of Last FDA inspection :

SECTION 3 DISTRIBUTOR INFORMATION (IF APPLICABLE) EDIT

Firm : RICK'S MEDICAL DEVICE FIRM(510k)	Address (P.O. Box not acceptable) : 11820 Parklawn Dr Ste 300 , Rockville , Maryland UNITED STATES , 20852
Registration number : 786898	

SECTION 4 PRODUCT INFORMATION EDIT

Will you be listing any refurbished or remanufactured products in this certificate? Yes No	
Are you the original manufacturer of this product(s)? Yes No	
This product(s) cannot be included on this application	
Trade name tn1	Proper name pn1
Marketing Status Exempt	



Trade name Trade Name2	Proper name Proper Name2
----------------------------------	------------------------------------

Marketing status K991735

Trade name Trade Name3	Proper name Proper Name3
----------------------------------	------------------------------------

Marketing status K974749

SECTION 5 WAS THE PRODUCT EVER RECALLED? **EDIT**

If "Yes" State the recall number and close-out date	Recall Number	Close-out Date :
Yes NO	Z-1039-05	

Trade name tn1	Proper name pn1
Close-out Letter details :	



Yes NO

Trade name Trade Name2	Proper name Proper Name2
----------------------------------	------------------------------------

Yes NO

Trade name Trade Name3	Proper name Proper Name3
----------------------------------	------------------------------------

SECTION 6 LIST COUNTRY(IES) FOR WHICH THE CERTIFICATES ARE REQUESTED **EDIT**

AFGHANISTAN
ALAND ISLANDS

SECTION 7 INDICATE WHAT PRODUCT INFORMATION SHOULD APPEAR ON THE CERTIFICATE **EDIT**

Manufacturer	Header Name	SubHeader Name
RICK'S MEDICAL DEVICE FIRM(510k)	Name of Owner Operator	Formerly Known As
Distributor	Header Name	SubHeader Name
RICK'S MEDICAL DEVICE FIRM(510k)	Name of Distributor	Manufactured For

Products Grouping

Extracting forceps , American Pattern , Fig A 151 S Pillers , Endo notched Locking Needle holders, CRILE-WOOD , 15cm Needle holders, DERF , 12.5cm Needle holders, MAYO-HEGAR , 16cm Rubberdam punch , IVORY Rubberdam punch , AINSWORTH Rubberdam clamp forceps ; BREWER	RICK'S MEDICAL DEVICE FIRM(510k)- 786898(Manufacturer)
--	---

Hemostatic forceps , KELLY , 14cm
 Hemostatic forceps , KELLY , 14cm , Curved
 Cheek retractors , CAEWOOD-MINNESOTA , 16cm
 Crown Scissors , BEEBEE , 10.5 cm
 Gum Scissors , LA-GRANGE , 11,5 cm , Sharp-Sharp , S-shape.
 Root Elevators , FLOHR L
 Root Elevators , CRYER L
 Raspatories , FREER , 18.5 cm
 C.S. Mirror #4
 C.S. Mirror #4 12 pack
 C.S. Mirror #5
 C.S. Mirror #5 12 Pack
 Gracey Deep Pocket 1-2 xp 3/8" Resin
 Gracey Deep Pocket 1-2 xp 3/8" Stainless
 Gracey Deep Pocket 3-4 xp 3/8" Resin
 Gracey Deep Pocket 3-4 xp 3/8" Stainless
 Cassette SL5 (5 Instr)
 Cassette SL5 (7 Instr - no rack)
 Cassette 108(8 Instr)
 Cassette 108 utility (8 Instr)
 Cassette 108 Removable Rack(8-16 Instr)
 Cassette 109 W/12 Slots



Probe 1 Yellow 7/32" stainless
 Probe 1 Yellow 3/8 " Resin
 Probe 12 Yellow 7/32 " Resin
 Probe 12 Yellow 7/32 " Stainless
 Explorer 23 (SE) 3/8" Resin
 Explorer 2 (DE) 3/8" Resin
 Explorer 3 (SE) 7/32" Stainless
 Curette Columbia 12-14 xp 3/8" Resin
 Curette Columbia 12-14 xp 3/8" Stainless
 Curette Columbia 12-14 xp 7/32" Resin
 Waxing PKT 1 1/4" Stainless

RICK'S MEDICAL DEVICE FIRM(510k)-
 786898(Manufacturer)
 RICK'S MEDICAL DEVICE FIRM(510k)-
 786898(Distributor)

SECTION 8 SHOULD THE COUNTRY DESTINATION BE LISTED ON THE CERTIFICATE?

EDIT

(*Note* : CDRH does not list a specific country on a certificate.)

Should the country destination be listed on the certificate ? Yes No

Indicate the total number of certificates requested: 12

SECTION 9 EXPORTER'S CERTIFICATION STATEMENT

EDIT

The undersigned verifies that all ingredients are approved for use by FDA or appear on the GRAS list, and each product is intended for human consumption and is available for sale in the U.S. without restriction.

Primary Facility : RICK'S MEDICAL DEVICE FIRM(510k) - Manufacturer

Name: Test Name

Title: Test Title

I Agree

Date: 08/31/2012

RICK'S MEDICAL DEVICE
 FIRM(510k)

[1346441380299_162-8-2012_cert.pdf](#)

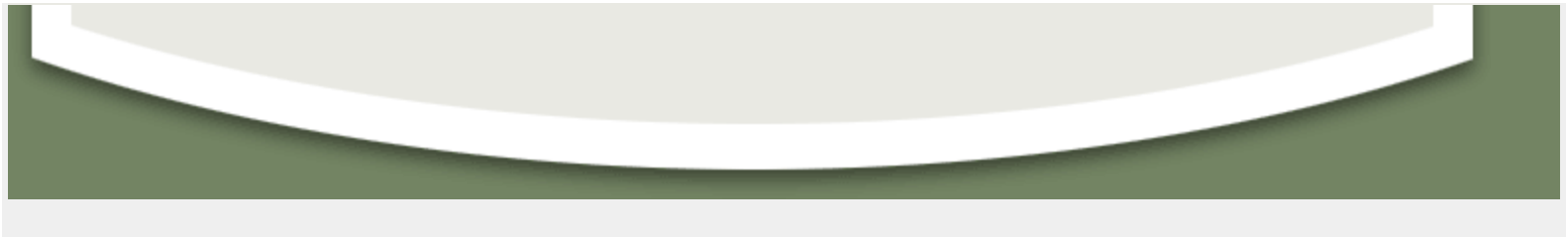
Not For Public Disclosure

Back to Main


Cancel & Start Again

Print Application

Submit





Get Help 

..... ENTER APPLICATION SUCCESSFUL!

Your Application Number is 337-8-2012

Please keep the Application number for your records. The Application number is required for all communications with FDA regarding this application. Please refer to the help section for more details.

Note: Processing the application will not begin until a complete request package has been received.

[Back to Main](#)

[>> View Complete Application](#)


[Get Help ?](#)

Date : 08/31/2012

Created Date: 08/31/2012

Certificate Type : Certificate to Foreign Government (CFG)

Application Number : 337-8-2012

Application Status : Received

SECTION 1 REQUESTOR INFORMATION

Name :Mr. Vijay Maringanti		Address : 11820 Parklawn Dr Ste 300 , Rockville , Maryland UNITED STATES , 20852	
Firm : gnsi			
Telephone Number : 301- 4656565	FAX Number:	Firm Tax ID code: 12 - 1211111	Email address: vijayasarithi.maringanti@fda. hhs.gov

SECTION 2 MANUFACTURER INFORMATION

Firm: GNSI - Class I Exempt Only With Inspection	Address (P.O. Box not acceptable): 311 W Side Dr Apt 301 , Gaithersburg , Maryland UNITED STATES , 20878
Registration number:	
License number (if applicable):	Date of Last FDA inspection: 03/01/2011
>>	

SECTION 3 DISTRIBUTOR INFORMATION (IF APPLICABLE)

Firm: RICK'S MEDICAL DEVICE FIRM(510k)	Address (P.O. Box not acceptable): 11820 Parklawn Dr Ste 300 , Rockville , Maryland UNITED STATES , 20852
Registration number: 786898	

SECTION 4 PRODUCT INFORMATION

Will you be listing any refurbished or remanufactured products in this certificate? Yes No	
Are you the original manufacturer of this product(s)? Yes No	
This product(s) cannot be included on this application	
Trade name tn1	Proper name pn1
Marketing status Exempt	
>>	
Trade name Trade Name3	Proper name Proper Name3
Marketing status K974749	

Trade name Trade Name2	Proper name Proper Name2
Marketing status K991735	

SECTION 5 WAS THE PRODUCT EVER RECALLED ?

If "Yes" State the recall number and close-out date	Recall number	Close-out Date:
Yes NO	Z-1039-05	
Trade name tn1	Proper name pn1	
Close-out Letter details :		
⌄		
Yes NO		
Trade name Trade Name3	Proper name Proper Name3	
Yes NO		
Trade name Trade Name2	Proper name Proper Name2	

SECTION 6 LIST COUNTRY(IES) FOR WHICH THE CERTIFICATES ARE REQUESTED

ALAND ISLANDS AFGHANISTAN	
------------------------------	--

SECTION 7 INDICATE WHAT PRODUCT INFORMATION SHOULD APPEAR ON THE CERTIFICATE

Manufacturer	Header Name	SubHeader Name
RICK'S MEDICAL DEVICE FIRM(510k)	Name of Owner Operator	Formerly Known As
Distributor	Header Name	SubHeader Name
RICK'S MEDICAL DEVICE FIRM(510k)	Name of Distributor	Manufactured For
Products Grouping		
Extracting forceps , American Pattern , Fig A 151 S Pillars , Endo notched Locking Needle holders, CRILE-WOOD , 15cm Needle holders, DERF , 12.5cm Needle holders, MAYO-HEGAR , 16cm Rubberdam punch , IVORY Rubberdam punch , AINSWORTH Rubberdam clamp forceps ; BREWER Hemostatic forceps , KELLY , 14cm Hemostatic forceps , KELLY , 14cm , Curved Cheek retractors , CAEWOOD-MINNESOTA , 16cm Crown Scissors , BEEBEE , 10.5 cm Gum Scissors , LA-GRANGE , 11,5 cm , Sharp-Sharp , S-shape. Root Elevators , FLOHR L Root Elevators , CRYER L	RICK'S MEDICAL DEVICE FIRM(510k)- 786898 (Manufacturer)	

Raspatories , FREER , 18.5 cm
 C.S. Mirror #4
 C.S. Mirror #4 12 pack
 C.S. Mirror #5
 C.S. Mirror #5 12 Pack
 Gracey Deep Pocket 1-2 xp 3/8" Resin
 Gracey Deep Pocket 1-2 xp 3/8" Stainless
 Gracey Deep Pocket 3-4 xp 3/8" Resin
 Gracey Deep Pocket 3-4 xp 3/8" Stainless
 Cassette SL5 (5 Instr)
 Cassette SL5 (7 Instr - no rack)
 Cassette 108(8 Instr)
 Cassette 108 utility (8 Instr)
 Cassette 108 Removable Rack(8-16 Instr)
 Cassette 109 W/12 Slots



Probe 1 Yellow 7/32" stainless
 Probe 1 Yellow 3/8 " Resin
 Probe 12 Yellow 7/32 " Resin
 Probe 12 Yellow 7/32 " Stainless
 Explorer 23 (SE) 3/8" Resin
 Explorer 2 (DE) 3/8" Resin
 Explorer 3 (SE) 7/32" Stainless
 Curette Columbia 12-14 xp 3/8" Resin
 Curette Columbia 12-14 xp 3/8" Stainless
 Curette Columbia 12-14 xp 7/32" Resin
 Waxing PKT 1 1/4" Stainless

RICK'S MEDICAL DEVICE FIRM(510k)-
 786898 (Manufacturer)
 RICK'S MEDICAL DEVICE FIRM(510k)-
 786898 (Distributor)

SECTION 8 SHOULD THE COUNTRY DESTINATION BE LISTED ON THE CERTIFICATE?

(**Note** : CDRH does not list a specific country on a certificate.)

Should the country destination be listed on the certificate? Yes No

Indicate the total number of certificates requested: 12

SECTION 9 EXPORTER'S CERTIFICATION STATEMENT

The undersigned verifies that all ingredients are approved for use by FDA or appear on the GRAS list, and each product is intended for human consumption and is available for sale in the U.S. without restriction.

Primary facility: RICK'S MEDICAL DEVICE FIRM(510k)-Manufacturer

Name: Test Name

Title: Test Title

I Agree

Date: 08/31/2012

RICK'S MEDICAL DEVICE FIRM(510k)

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Print Application



Get Help 

SEARCH APPLICATION

APPLICATION
NUMBER:

REGISTRATION
NUMBER:

OWNER
OPERATOR
NUMBER:

FACILITY NAME

Manufacturer

ADDRESS, LINE 1:

ADDRESS, LINE 2:

CITY:

STATE / [Click here to select a State / Province / Territory](#)
PROVINCE
/TERRITORY:

ZIP:

COUNTRY/AREA: --Please select Country--

APPLICATION
STATUS: Received

>> Reset

>> Submit

<< Back to Main



Get Help 

SEARCH APPLICATIONS - SEARCH RESULTS

Search Results - **Total Applications: 1**

The following Applications match your search criteria. You can use the up and down arrows to sort the application list.

Page 1 of 1

▲ Application Number ▼	▲ Date Of Application ▼	▲ Status ▼	▲ Certificate Type ▼
337-8-2012	2012-08-31 15:30:31.0	Received	Certificate to Foreign Government (CFG)

>> Modify Application

<< Back

>> New Search



[Get Help](#) 

Please select from the following options

***Modify Options :**

- Update Recall Close-out Letter / ECS Document
- Update the number of Certificates
- Cancel the application

[Back to Main](#)

[Continue](#)



[Get Help](#) 

Please select from the following options


***Modify Options :**

- Update Recall Close-out Letter / ECS Document
- Update the number of Certificates
- Cancel the application

[Back to Main](#)

[Continue](#)



Get Help 

Select	Application Number	Date of Application	Certificate Type	Status
	337-8-2012	08/31/2012	Certificate to Foreign Government (CFG)	Return for Action





Get Help

Please review your application. If all information is correct, click the **Submit** button below. To make changes to a section, click the **Edit** button for that section.

Date: 08/31/2012

Created Date: 08/31/2012

Certificate Type : Certificate to Foreign Government (CFG)

Application Number : 337-8-2012

Application Status : Return for Action

SECTION 1 REQUESTOR INFORMATION

Name :Mr. Vijay Maringanti		Address : 11820 Parklawn Dr Ste 300 , Rockville , Maryland UNITED STATES , 20852	
Firm : gnsi			
Telephone number : 301-4656565	FAX Number :	Firm Tax ID code : 12 - 1211111	Email address : vijayasarathi.maringanti@fda.hhs.gov

SECTION 2 MANUFACTURER INFORMATION

Firm: GNSI - Class I Exempt Only With Inspection	Address (P.O. Box not acceptable): 311 W Side Dr Apt 301 , Gaithersburg , Maryland UNITED STATES , 20878
Registration number:	
License number (if applicable):	Date of Last FDA inspection: 03/01/2011

SECTION 3 DISTRIBUTOR INFORMATION (IF APPLICABLE)

Firm: RICK'S MEDICAL DEVICE FIRM(510k)	Address (P.O. Box not acceptable): 11820 Parklawn Dr Ste 300 , Rockville , Maryland UNITED STATES , 20852
Registration number: 786898	

SECTION 4 PRODUCT INFORMATION

Will you be listing any refurbished or remanufactured products in this certificate? Yes No

Are you the original manufacturer of this product(s)? Yes No


This product(s) cannot be included on this application

Trade name tn1	Proper name pn1
-------------------	--------------------

Marketing status Exempt

SECTION 5 WAS THE PRODUCT EVER RECALLED?

EDIT

If "Yes" State the recall number and close-out date	Recall Number	Close-out Date:
Yes NO	Z-1039-05	
Close-out Letter details :		
		

SECTION 6 LIST COUNTRY(IES) FOR WHICH THE CERTIFICATES ARE REQUESTED

AFGHANISTAN
ALAND ISLANDS

SECTION 7 INDICATE WHAT PRODUCT INFORMATION SHOULD APPEAR ON THE CERTIFICATE

Manufacturer	Header Name	SubHeader Name
RICK'S MEDICAL DEVICE FIRM(510k)	Name of Owner Operator	Formerly Known As
Distributor	Header Name	SubHeader Name
RICK'S MEDICAL DEVICE FIRM(510k)	Name of Distributor	Manufactured For

Products Grouping

Extracting forceps , American Pattern , Fig A 151 S Pillers , Endo notched Locking Needle holders, CRILE-WOOD , 15cm Needle holders, DERF , 12.5cm Needle holders, MAYO-HEGAR , 16cm Rubberdam punch , IVORY Rubberdam punch , AINSWORTH Rubberdam clamp forceps ; BREWER Hemostatic forceps , KELLY , 14cm Hemostatic forceps , KELLY , 14cm , Curved Cheek retractors , CAEWOOD-MINNESOTA , 16cm Crown Scissors , BEEBEE , 10.5 cm Gum Scissors , LA-GRANGE , 11,5 cm , Sharp-Sharp , S-shape. Root Elevators , FLOHR L Root Elevators , CRYER L Raspatories , FREER , 18.5 cm C.S. Mirror #4 C.S. Mirror #4 12 pack C.S. Mirror #5 C.S. Mirror #5 12 Pack Gracey Deep Pocket 1-2 xp 3/8" Resin Gracey Deep Pocket 1-2 xp 3/8" Stainless Gracey Deep Pocket 3-4 xp 3/8" Resin Gracey Deep Pocket 3-4 xp 3/8" Stainless Cassette SL5 (5 Instr) Cassette SL5 (7 Instr - no rack) Cassette 108(8 Instr) Cassette 108 utility (8 Instr) Cassette 108 Removable Rack(8-16 Instr) Cassette 109 W/12 Slots	RICK'S MEDICAL DEVICE FIRM(510k)-786898 (Manufacturer)
--	--

SECTION 8 SHOULD THE COUNTRY DESTINATION BE LISTED ON THE CERTIFICATE?

(**Note** : CDRH does not list a specific country on a certificate.)

Should the country destination be listed on the certificate ? Yes No

Indicate the total number of certificates requested: 12

SECTION 9 EXPORTER'S CERTIFICATION STATEMENT

EDIT

The undersigned verifies that all ingredients are approved for use by FDA or appear on the GRAS list, and each product is intended for human consumption and is available for sale in the U.S. without restriction.

Primary Facility: RICK'S MEDICAL DEVICE FIRM(510k)-Manufacturer

Name: Test Name

Title: Test Title

I Agree

Date: 08/31/2012

RICK'S MEDICAL DEVICE
FIRM(510k)

[1346441380299_162-8-2012_cert.pdf](#)

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Back

Cancel & Start Again

Print Application

Submit



Get Help

Continue

SECTION 9 EXPORTER'S CERTIFICATION STATEMENT

Each facility intended to be printed on the certificate must have a corresponding Exporter's Certification Statement (ECS). Please upload the ECS to the corresponding facility. You will not be able to submit the application without the ECS for each facility.

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The total file size of all ECS attachments cannot exceed 50MB (Megabytes).
The accepted file formats include pdf, bmp, jpeg, gif, png, tiff, doc, and docx.

Name of the Manufacturer(s)	
RICK'S MEDICAL DEVICE FIRM(510k)	no file selected <input type="button" value="Upload"/>

Name of the Distributor(s)	
*RICK'S MEDICAL DEVICE FIRM(510k)	1346441380299_162-8-2012_cert.pdf <input type="button" value="Remove"/>

Continue



[Get Help](#) 

The Application Number 337-8-2012 is modified successfully

[Back to Main](#)



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Please select from the following options

***Modify Options :**

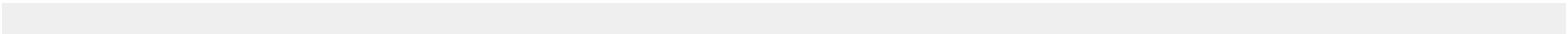
- Update Recall Close-out Letter / ECS Document
- Update the number of Certificates
- Cancel the application

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[Get Help ?](#)

Select	Application Number	Date of Application	Certificate Type	Status
	337-8-2012	08/31/2012	Certificate to Foreign Government (CFG)	Ready for Review
	317-8-2012	08/29/2012	Certificate to Foreign Government (CFG)	Ready for Review
	221-8-2012	08/19/2012	Certificate to Foreign Government (CFG)	Ready for Review
	262-8-2012	08/22/2012	Certificate to Foreign Government (CFG)	Ready for Review
	225-8-2012	08/20/2012	Certificate to Foreign Government (CFG)	Ready for Review
	213-8-2012	08/16/2012	Certificate to Foreign Government (CFG)	Ready for Review
	331-8-2012	08/31/2012	Certificate to Foreign Government (CFG)	Ready for Review
	311-8-2012	08/29/2012	Certificate to Foreign Government (CFG)	Ready for Review
	238-8-2012	08/20/2012	Certificate to Foreign Government (CFG)	Ready for Review
	288-8-2012	08/30/2012	Certificate to Foreign Government (CFG)	Ready for Review





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Please review your application. If all information is correct, click the **Submit** button below. To make changes to a section, click the **Edit** button for that section.

Date: 08/31/2012

Created Date: 08/31/2012

Certificate Type : Certificate to Foreign Government (CFG)

Application Number : 337-8-2012

Application Status : Ready for Review

SECTION 1 REQUESTOR INFORMATION

Name :Mr. Vijay Maringanti		Address : 11820 Parklawn Dr Ste 300 , Rockville , Maryland UNITED STATES , 20852	
Firm : gnsi			
Telephone number : 301-4656565	FAX Number :	Firm Tax ID code : 12 - 1211111	Email address : vijayasarathi.maringanti@fda.hhs.gov

SECTION 2 MANUFACTURER INFORMATION

Firm: RICK'S MEDICAL DEVICE FIRM(510k)	Address (P.O Box not acceptable): 11820 Parklawn Dr Ste 300 , Rockville , Maryland UNITED STATES , 20852
Registration number: 786898	
License number (if applicable):	Date of Last FDA inspection:

SECTION 3 DISTRIBUTOR INFORMATION (IF APPLICABLE)

Firm: RICK'S MEDICAL DEVICE FIRM(510k)	Address (P.O. Box not acceptable): 11820 Parklawn Dr Ste 300 , Rockville , Maryland UNITED STATES , 20852
Registration number: 786898	

SECTION 4 PRODUCT INFORMATION

Will you be listing any refurbished or remanufactured products in this certificate? Yes No

Are you the original manufacturer of this product(s)? Yes No

This product(s) cannot be included on this application

Trade name Trade Name3	Proper name Proper Name3
Marketing status K974749	

SECTION 5 WAS THE PRODUCT EVER RECALLED?

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If "Yes" State the recall number and close-out date	Recall Number	Close-out Date:
Yes NO		

SECTION 6 LIST COUNTRY(IES) FOR WHICH THE CERTIFICATES ARE REQUESTED

ALAND ISLANDS	
AFGHANISTAN	

SECTION 7 INDICATE WHAT PRODUCT INFORMATION SHOULD APPEAR ON THE CERTIFICATE

Manufacturer	Header Name	SubHeader Name
RICK'S MEDICAL DEVICE FIRM(510k)	Name of Owner Operator	Formerly Known As
Distributor	Header Name	SubHeader Name
RICK'S MEDICAL DEVICE FIRM(510k)	Name of Distributor	Manufactured For

Products Grouping

Extracting forceps , American Pattern , Fig A 151 S Pillers , Endo notched Locking Needle holders, CRILE-WOOD , 15cm Needle holders, DERF , 12.5cm Needle holders, MAYO-HEGAR , 16cm Rubberdam punch , IVORY Rubberdam punch , AINSWORTH Rubberdam clamp forceps ; BREWER Hemostatic forceps , KELLY , 14cm Hemostatic forceps , KELLY , 14cm , Curved Cheek retractors , CAEWOOD-MINNESOTA , 16cm Crown Scissors , BEEBEE , 10.5 cm Gum Scissors , LA-GRANGE , 11,5 cm , Sharp-Sharp , S-shape. Root Elevators , FLOHR L Root Elevators , CRYER L Raspatories , FREER , 18.5 cm C.S. Mirror #4 C.S. Mirror #4 12 pack C.S. Mirror #5 C.S. Mirror #5 12 Pack Gracey Deep Pocket 1-2 xp 3/8" Resin Gracey Deep Pocket 1-2 xp 3/8" Stainless Gracey Deep Pocket 3-4 xp 3/8" Resin Gracey Deep Pocket 3-4 xp 3/8" Stainless Cassette SL5 (5 Instr) Cassette SL5 (7 Instr - no rack) Cassette 108(8 Instr) Cassette 108 utility (8 Instr) Cassette 108 Removable Rack(8-16 Instr) Cassette 109 W/12 Slots	RICK'S MEDICAL DEVICE FIRM(510k)-786898 (Manufacturer)
--	--

SECTION 8 SHOULD THE COUNTRY DESTINATION BE LISTED ON THE CERTIFICATE? **EDIT**

(**Note** : CDRH does not list a specific country on a certificate.)

Should the country destination be listed on the certificate ? Yes No

Indicate the total number of certificates requested: 12

SECTION 9 EXPORTER'S CERTIFICATION STATEMENT

The undersigned verifies that all ingredients are approved for use by FDA or appear on the GRAS list, and each product is intended for human consumption and is available for sale in the U.S. without restriction.

Primary Facility: RICK'S MEDICAL DEVICE FIRM(510k)-Manufacturer

Name: Test Name

Title: Test Title

I Agree

Date: 08/31/2012


RICK'S MEDICAL DEVICE
FIRM(510k)

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SECTION 8 SHOULD THE COUNTRY DESTINATION BE LISTED
ON THE CERTIFICATE?

(**Note** : CDRH does not list a specific country on a certificate.)

Should the country destination be listed on the certificate ? Yes No

Indicate the total number of certificates requested :

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Please review your application. If all information is correct, click the **Submit** button below. To make changes to a section, click the **Edit** button for that section.

Date: 08/31/2012

Created Date: 08/31/2012

Certificate Type : Certificate to Foreign Government (CFG)

Application Number : 337-8-2012

Application Status : Ready for Review

SECTION 1 REQUESTOR INFORMATION

Name :Mr. Vijay Maringanti		Address : 11820 Parklawn Dr Ste 300 , Rockville , Maryland UNITED STATES , 20852	
Firm : gnsi			
Telephone number : 301-4656565	FAX Number :	Firm Tax ID code : 12 - 1211111	Email address : vijayasarathi.maringanti@fda.hhs.gov

SECTION 2 MANUFACTURER INFORMATION

Firm: RICK'S MEDICAL DEVICE FIRM(510k)	Address (P.O. Box not acceptable): 11820 Parklawn Dr Ste 300 , Rockville , Maryland UNITED STATES , 20852
Registration number: 786898	
License number (if applicable):	Date of Last FDA inspection:

SECTION 3 DISTRIBUTOR INFORMATION (IF APPLICABLE)

Firm: RICK'S MEDICAL DEVICE FIRM(510k)	Address (P.O. Box not acceptable): 11820 Parklawn Dr Ste 300 , Rockville , Maryland UNITED STATES , 20852
Registration number: 786898	

SECTION 4 PRODUCT INFORMATION

Will you be listing any refurbished or remanufactured products in this certificate? Yes No

Are you the original manufacturer of this product(s)? Yes No

This product(s) cannot be included on this application

Trade name Trade Name3	Proper name Proper Name3
Marketing status K974749	

SECTION 5 WAS THE PRODUCT EVER RECALLED?

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If "Yes" State the recall number and close-out date	Recall Number	Close-out Date:
Yes NO		

SECTION 6 LIST COUNTRY(IES) FOR WHICH THE CERTIFICATES ARE REQUESTED

ALAND ISLANDS	
AFGHANISTAN	

SECTION 7 INDICATE WHAT PRODUCT INFORMATION SHOULD APPEAR ON THE CERTIFICATE

Manufacturer	Header Name	SubHeader Name
RICK'S MEDICAL DEVICE FIRM(510k)	Name of Owner Operator	Formerly Known As
Distributor	Header Name	SubHeader Name
RICK'S MEDICAL DEVICE FIRM(510k)	Name of Distributor	Manufactured For

Products Grouping

Extracting forceps , American Pattern , Fig A 151 S Pillers , Endo notched Locking Needle holders, CRILE-WOOD , 15cm Needle holders, DERF , 12.5cm Needle holders, MAYO-HEGAR , 16cm Rubberdam punch , IVORY Rubberdam punch , AINSWORTH Rubberdam clamp forceps ; BREWER Hemostatic forceps , KELLY , 14cm Hemostatic forceps , KELLY , 14cm , Curved Cheek retractors , CAEWOOD-MINNESOTA , 16cm Crown Scissors , BEEBEE , 10.5 cm Gum Scissors , LA-GRANGE , 11,5 cm , Sharp-Sharp , S-shape. Root Elevators , FLOHR L Root Elevators , CRYER L Raspatories , FREER , 18.5 cm C.S. Mirror #4 C.S. Mirror #4 12 pack C.S. Mirror #5 C.S. Mirror #5 12 Pack Gracey Deep Pocket 1-2 xp 3/8" Resin Gracey Deep Pocket 1-2 xp 3/8" Stainless Gracey Deep Pocket 3-4 xp 3/8" Resin Gracey Deep Pocket 3-4 xp 3/8" Stainless Cassette SL5 (5 Instr) Cassette SL5 (7 Instr - no rack) Cassette 108(8 Instr) Cassette 108 utility (8 Instr) Cassette 108 Removable Rack(8-16 Instr) Cassette 109 W/12 Slots	RICK'S MEDICAL DEVICE FIRM(510k)-786898 (Manufacturer)
--	--

SECTION 8 SHOULD THE COUNTRY DESTINATION BE LISTED ON THE CERTIFICATE? **EDIT**

(**Note** : CDRH does not list a specific country on a certificate.)

Should the country destination be listed on the certificate ? Yes No

Indicate the total number of certificates requested: 18

SECTION 9 EXPORTER'S CERTIFICATION STATEMENT

The undersigned verifies that all ingredients are approved for use by FDA or appear on the GRAS list, and each product is intended for human consumption and is available for sale in the U.S. without restriction.

Primary Facility: RICK'S MEDICAL DEVICE FIRM(510k)-Manufacturer

Name: Test Name

Title: Test Title

I Agree

Date: 08/31/2012

RICK'S MEDICAL DEVICE
FIRM(510k)

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Please select from the following options

***Modify Options :**

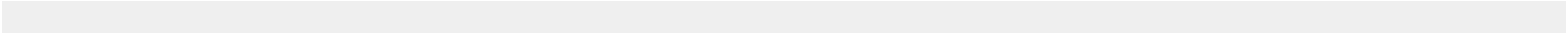
- Update Recall Close-out Letter / ECS Document
- Update the number of Certificates
- Cancel the application

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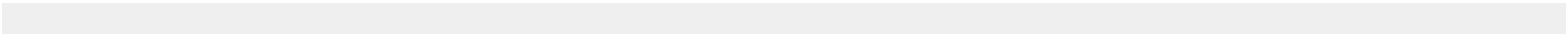
Select	Application Number	Date of Application	Certificate Type	Status
	311-8-2012	08/29/2012	Certificate to Foreign Government (CFG)	Ready for Review
	221-8-2012	08/19/2012	Certificate to Foreign Government (CFG)	Ready for Review
	337-8-2012	08/31/2012	Certificate to Foreign Government (CFG)	Ready for Review
	262-8-2012	08/22/2012	Certificate to Foreign Government (CFG)	Ready for Review
	317-8-2012	08/29/2012	Certificate to Foreign Government (CFG)	Ready for Review
	331-8-2012	08/31/2012	Certificate to Foreign Government (CFG)	Ready for Review
	238-8-2012	08/20/2012	Certificate to Foreign Government (CFG)	Ready for Review
	225-8-2012	08/20/2012	Certificate to Foreign Government (CFG)	Ready for Review
	288-8-2012	08/30/2012	Certificate to Foreign Government (CFG)	Ready for Review
	213-8-2012	08/16/2012	Certificate to Foreign Government (CFG)	Ready for Review






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