

Device Registration and Listing Module

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OMB Burden Statement:

Public reporting burden for this collection of information on form FDA 3673 is estimated to be 0.50 hours per response for the purpose of firms annually registering their establishment and 0.25 hours per response for the purpose of firms annually listing their devices. These estimates are based on FDA's experience, data from the device registration and listing database, and our estimates of the time needed to complete other previously required forms.

Send comments regarding this burden estimate or another aspect of this collection of information, including suggestions for reducing this burden to:

FDA PRA Staff,

Food and Drug Administration,

8455 Colesville Rd.,

COLE-14526,

Silver Spring, MD 20993-0002,

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FDA Industry Systems - Accounts Management - Windows Internet Explorer

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Account Management <ul style="list-style-type: none">» Edit Account Profile» Change My Password» Update System Access» Create a Subaccount» Deactivate a Subaccount» Reactivate a Subaccount	Welcome You are logged in as fda15659 Welcome to the FDA Industry Systems. You are logged in to your account for company FDA <i>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.</i> FDA Unified Registration Listing Systems <table border="1"><tr><td>Food Facility Registration</td><td>Device Registration & Listing</td></tr><tr><td>Shell Egg Registration</td><td>Drug Facility Registration</td></tr><tr><td>Low Acid Canned Food</td><td></td></tr></table> Other FDA Systems <table border="1"><tr><td>Prior Notice</td></tr></table>	Food Facility Registration	Device Registration & Listing	Shell Egg Registration	Drug Facility Registration	Low Acid Canned Food		Prior Notice
Food Facility Registration	Device Registration & Listing							
Shell Egg Registration	Drug Facility Registration							
Low Acid Canned Food								
Prior Notice								

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Device Registration and Listing Module System - Windows Internet Explorer

https://www.access.fda.gov/drlm/mainMenu1.htm;jsessionid=0aaa516730d90fa58b94b9444a0f8beca2e215eef01b.e3qRa3qKb30Qe34TaNaTbN4Ka41ynknvrkLOIQzNp65In

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DRLM

Device Registration & Listing Module



FURLS HOME
DRLM HOME

DRLM Main Menu

Get Help ?

Important Notice: If you are required to pay the establishment registration user fee, you must visit the [FDA User Fee website](#) and pay for your facility prior to registering. If you are required to pay the fee and have not yet received your Payment Confirmation Number (PCN), you will not be able to register your facility and will need to return and re-enter all information for the facility.


Who Must Pay: A facility that is required to register that manufactures a device for itself or another party, performs contract sterilization for another party, reprocesses single-use devices, or develops specifications for a device that is manufactured by another party must pay the annual registration user fee. For more detailed information about who must pay the fee, please [click here](#).


- [Annual Registration](#)
(Annual Review of Device Registration and Listing Information)
- [View Your Registration and Listing Information](#)
- [Change Registration Information for a Facility](#)


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 [Cancel, Deactivate, or Reactivate a Facility Registration](#)

 [Change the Official Correspondent for a Facility](#)

 [Register a **New** Medical Device Facility](#)

 Create Listings for Medical Devices

 [Change, Cancel, or Reactivate Listings](#)

 [Transfer Ownership of Devices or Facilities](#)

DRLM

Device Registration & Listing Module



Register Your Facility

Register a New Facility

Get Help ?

If you already have a Registration Number or Owner Operator Number, please enter it in the space below and click Search.
If you do not have a Registration Number or Owner Operator Number, click No Existing Registration or OO Number.

Registration Number OR Owner Operator Number

If an establishment at this address has previously been registered with FDA as a device facility, but you do not know your Registration Number or Owner Operator Number, please send an email to regist@cdrh.fda.gov for assistance. Do not create a new registration if a medical device facility has ever been registered at your address.

< CANCEL - RETURN to MAIN MENU

> SEARCH

> NO EXISTING REGISTRATION OR OO NUMBER

Using FURLS to Register Your Facility - Windows Internet Explorer

https://www.access.fda.gov/drlm/drlm.htm?_flowExecutionKey=_c71486106-FDE9-6793-86C1-F2F09EE3A3B7_k94C4DAAB-07CC-9388-A438-8BD0AB647186

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Register Your Facility Get Help ?

Registration Requirements

Important Notice: If you are required to pay the establishment registration user fee, you must visit the [FDA User Fee website](#) and pay for your facility prior to registering. If you are required to pay the fee and have not yet received your Payment Confirmation Number (PCN), you will not be able to register your facility and will need to return and re-enter all information for the facility.

Who Must Pay: A facility that is required to register that manufactures a device for itself or another party, performs contract sterilization for another party, reprocesses single-use devices, or develops specifications for a device that is manufactured by another party must pay the annual registration user fee. For more detailed information about who must pay the fee, please [click here](#).

On the next few pages, you will need to enter the business name and address of your medical device facility. If your facility is located outside of the United States, you will also need to enter information about your U.S. Agent. With the exception of facilities that only act as initial importers of medical devices, you will need to create a listing for each product that you manufacture or process at your facility.

To enter a listing, you will need to identify whether your product is exempt from [premarket notification and approval](#).

If your product is exempt, you will:

- Identify the appropriate [product code\(s\)](#)
- Enter the proprietary name(s) under which the product is marketed
- Identify the [activities](#) that you perform on or to the product(s)

If your product is not exempt, you will:

- Enter the premarket submission number(s) associated with your product(s)
- Enter the proprietary name(s) under which the product is marketed
- Identify the [activities](#) that you perform on or to the product(s)

[< CANCEL - RETURN to MAIN MENU](#) [> REGISTER MY FACILITY](#)

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DRLM

Device Registration & Listing Module



Register Your Facility

Transfer Of Ownership?

Get Help ?

Is this registration the result of buying a registered facility from another company or merging with another company at this location?

YES NO

[← BACK](#) [← CANCEL - RETURN to MAIN MENU](#) [> CONTINUE REGISTRATION](#)

Device Registration & Listing Module

Register Your Facility

Owner/Operator and Official Correspondent Information

Get Help ?

The Owner/Operator and Official Correspondent information that you entered when you created or updated your FURLS account is displayed below. To make changes to either the Owner Operator or the Official Correspondent information, you will need to exit the DRLM section of FURLS and [return to Account Management](#).

Owner/Operator Information

Contact Name: David Racine
Company: FDA
Address: 10225 Malvern Court
Manassas, VA 20110, UNITED STATES
Telephone: 703-3333333
Fax:
E-mail: david.racine@fda.hhs.gov

Official Correspondent Information

Testsubaccount test

Contact Name: Testsubaccount test
Company: test
Address: 20 Main Street,
Manassas, VA 20110, UNITED STATES
Telephone: 240-2780640
Fax:
E-mail: dwr@cdrh.fda.gov

Register Your Facility

Fields marked with an asterisk (*) are required.

Establishment Information Same as Owner/Operator Same as Official Correspondent

Choose Country where Facility is Located:* UNITED STATES

Facility Name:* FDA

Address Line 1:* 10220 Malvern Court

Address Line 2:

Zip Code:* 20110

City:* Manassas

State:* Virginia

Phone: Area/City Code: Phone Number: Extension:
703 3333333

Fax: Area/City Code: Fax Number:

Facility URL:

Other Business Trade Name(s):

Initial Importer Question Screen - Windows Internet Explorer


https://www.access.fda.gov/drlm/drlm.htm?_flowExecutionKey=_c71486106-FDE9-6793-86C1-F2F09EE3A3B7_kCOD3903F-A838-E924-D1B7-A7D116B28CD2

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DRLM

Device Registration & Listing Module



FDA FURLS HOME
DRLM HOME

Register Your Facility

Initial Importer Question Get Help ?

FACILITY: FDA, SILVER SPRING, MARYLAND, UNITED STATES

Does this facility import medical devices to the United States from another Country/Area?

YES NO

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Device Registration & Listing Module

Register Your Facility

Identify Facility's Products

Get Help ?

FACILITY: *FDA, MANASSAS, VIRGINIA, UNITED STATES*

The products shown below have previously been listed by your company for other facilities. Select one or more products from the list below for this Facility or click "ADD NEW PRODUCT" to create a listing for a new product.

<input type="checkbox"/>	Listing Number	Listing Status	Premarket Submission Number/Type	Product Code(s)	Device Name	Registration Numbers
<input type="checkbox"/>	D004788	Active	K010880	CAF	NEBULIZER (DIRECT PATIENT INTERFACE)	Not Yet Assigned.
<input type="checkbox"/>	D004789	Active	K904717	CAF	NEBULIZER (DIRECT PATIENT INTERFACE)	Not Yet Assigned.

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> ADD NEW PRODUCT

> ADD SELECTED PRODUCTS TO THIS FACILITY

enter the Premarket Submission Number - Windows Internet Explorer

https://www.access.fda.gov/drlm/drlm.htm?_flowExecutionKey=_c71486106-FDE9-6793-86C1-F2F09EE3A3B7_kB063277B-52FB-C924-0CCA-0C2C651CB9FA

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Register Your Facility Get Help ?

Enter Product Number

FACILITY: FDA, SILVER SPRING, MARYLAND, UNITED STATES

Important Notice: If you are required to pay an annual registration user fee, you must visit the [FDA User Fee website](#) and pay the fee prior to registering your facility. To determine if you need to pay the fee, please [click here](#).

For the product you are listing, enter one of the following:

- Premarket Notification (510(k)) number
- Premarket Application (PMA) number
- Product Development Protocol (PDP) number
- Humanitarian Device Exemption (HDE) number
- Investigational New Drug (IND) number
- New Drug Application (NDA) number

If you believe the product you are listing falls under enforcement discretion or preamendment, please contact the CDRH Registration and Listing Helpdesk at reglist@cdrh.fda.gov.

If your device is exempt from FDA premarket notification requirements, leave the box empty and click "Continue".

Enter the Premarket Submission Number:

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Device Registration & Listing Module



Register Your Facility

Exporter or Importer Question

Get Help ?

FACILITY: *FDA, MANASSAS, VIRGINIA, UNITED STATES*

Is this device being manufactured solely for export to a foreign country?

YES NO

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> CONTINUE

DRLM

Device Registration & Listing Module



Register Your Facility

Exporter or Importer Question

[Get Help ?](#)

FACILITY: *FDA, MANASSAS, VIRGINIA, UNITED STATES*

Is this device being manufactured solely for export to a foreign country?

YES NO

[< BACK](#) [< CANCEL - RETURN to MAIN MENU](#) [> CONTINUE](#)

FACILITY: FDA, MANASSAS, VIRGINIA, UNITED STATES

Select Product Code(s)

Shorten your search by using the filter option. Type a word or words describing the device and click Filter. A list of product codes and names will appear below. If you already know the correct product code, type the product code in the box and click Filter. Once you have selected a product code, click Continue

Enter the Product Code or a word or words describing the device:

Displaying Page 1 of 1

	Medical Specialty	Product Code	Device/Product Name	Class	Premarket Submission Required
<input checked="" type="radio"/>	DENTAL	EJX	ANCHOR, PREFORMED	1	510(k) exempt
<input type="radio"/>	GENERAL AND PLASTIC SURGERY	NEH	ANCHOR, FASCIAL	2	510(k)
<input type="radio"/>	ORTHOPEDIC	NWN	Kit, laparoscopic, bone anchor, urethropexy	2	510(k)
<input type="radio"/>	ORTHOPEDIC	NOV	ANCHOR, SUTURE, BONE FIXATION, METALLIC	2	510(k)

None of the above. Request new product code.

FACILITY: FDA, MANASSAS, VIRGINIA, UNITED STATES

Select Product Code(s)

Shorten your search by using the filter option. Type a word or words describing the device and click Filter. A list of product codes and names will appear below. If you already know the correct product code, type the product code in the box and click Filter. Once you have selected a product code, click Continue

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Displaying Page 1 of 1

	Medical Specialty	Product Code	Device/Product Name	Class	Premarket Submission Required
<input checked="" type="radio"/>	DENTAL	EJX	ANCHOR, PREFORMED	1	510(k) exempt
<input type="radio"/>	GENERAL AND PLASTIC SURGERY	NEH	ANCHOR, FASCIAL	2	510(k)
<input type="radio"/>	ORTHOPEDIC	NWN	Kit, laparoscopic, bone anchor, urethropexy	2	510(k)
<input type="radio"/>	ORTHOPEDIC	NOV	ANCHOR, SUTURE, BONE FIXATION, METALLIC	2	510(k)

None of the above. Request new product code.


select facility types - Windows Internet Explorer
https://www.access.fda.gov/drlm/drlm.htm?_flowExecutionKey=_c71486106-FDE9-6793-86C1-F2F09EE3A3B7_kB2A950BC-BE6E-1A91-0512-BC0BD94EE447

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Device Registration & Listing Module



FURLS HOME
DRLM HOME

Register Your Facility
Select Activities for Listing(s) [Get Help ?](#)

FACILITY: FDA, SILVER SPRING, MARYLAND, UNITED STATES

Select all activities related to this device that are performed at your facility.

- Manufacture Medical Device*
- Develop Specifications But Do Not Manufacture At This Facility*
- Manufacture and Distribute Medical Device for Another Party (Contract Manufacturer)*
- Sterilize and Distribute Medical Device for Another Party (Contract Sterilizer)*
- Reprocess Single-Use Device*
- Repack or Relabel Medical Device
- Remanufacture Medical Device
- Export Device to the United States But Perform No Other Operation on Device
- Manufacture Device in the United States for Export Only*

*Requires payment of annual registration user fee.

Important Notice: If you are required to pay an annual registration user fee, you must visit the [FDA User Fee website](#) and pay the fee prior to registering your facility. To determine if you need to pay the fee, please [click here](#).

Proprietary Names

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Enter any proprietary or brand names that your product is distributed under, then click Continue.

Proprietary Name(s):

< Remove

^ Add Proprietary Name

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> CONTINUE

Device Registration & Listing Module

Register Your Facility Listings Summary

Get Help ?

FACILITY: FDA, MANASSAS, VIRGINIA, UNITED STATES

- Review the listings in the "Added Listing(s)" table below.
- Make corrections by selecting a listing and clicking "Edit Selected Listing."
- Add more listings by clicking "Add New product."

	Listing Number	Premarket Submission Number/Type	Product Code(s)	Device Name(s)	Activities	Proprietary Names
<input type="radio"/>	New Listing	Exempt	EJX	ANCHOR, PREFORMED	Manufacture Medical Device	Acme

> REMOVE this PRODUCT from FACILITY'S LISTINGS > EDIT SELECTED LISTING

< Go to OWNER OPERATOR LIST > ADD NEW PRODUCT

< CANCEL - RETURN to MAIN MENU > CONTINUE

Review Registration Screen - Windows Internet Explorer

https://www.access.fda.gov/drlm/drlm.htm?_flowExecutionKey=_c71486106-FDE9-6793-86C1-F2F09EE3A3B7_k957A6571-2363-2B11-B728-1C773E120696

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Device Registration & Listing Module



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Register Your Facility Get Help ?

Registration Review

FACILITY: *FDA, SILVER SPRING, MARYLAND, UNITED STATES*

Important Notice: If you are required to pay the establishment registration user fee, you must visit the [FDA User Fee website](#) and pay for your facility prior to registering. If you are required to pay the fee and have not yet received your Payment Confirmation Number (PCN), you will not be able to register your facility and will need to return and re-enter all information for the facility.

Who Must Pay: A facility that is required to register that manufactures a device for itself or another party, performs contract sterilization for another party, reprocesses single-use devices, or develops specifications for a device that is manufactured by another party must pay the annual registration user fee. For more detailed information about who must pay the fee, please [click here](#). If you have already registered for the current fiscal year, you do not need to provide your Payment Identification Number (PIN) and PCN again.

- Review the information that you provided for your facility.
- Make changes to your facility or listing information by clicking the Edit button at the top of the corresponding section.
- Make changes to Owner/Operator or Official Correspondent information by clicking Submit, then

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Review Registration Screen - Windows Internet Explorer

https://www.access.fda.gov/drlm/drlm.htm?_flowExecutionKey=_c71486106-FDE9-6793-86C1-F2F09EE3A3B7_k957A6571-2363-2B11-8728-1C773E120696

File Edit View Favorites Tools Help

- Make changes to your facility or listing information by clicking the Edit button at the top of the corresponding section.
- Make changes to Owner/Operator or Official Correspondent information by clicking Submit, then select "Return to Account Management" on the next page.

Facility [> EDIT](#)

Registration Number:
Initial Importer: N
Facility Name: FDA
Address: 10993 New Hampshire Ave.
Silver Spring, Maryland, 20993, UNITED STATES
Facility URL:
Other Business Trade Name(s):

Owner/Operator Information

Contact Name: David Gartner
Company: FDA
Address: 10993 New Hampshire Ave.
Silver Spring, MARYLAND, 20993, UNITED STATES
Telephone: 111-1111111
Fax:
E-mail: david.gartner@fda.hhs.gov

Official Correspondent Information

Contact Name: David Gartner

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Review Registration Screen - Windows Internet Explorer

https://www.access.fda.gov/drlm/drlm.htm?_flowExecutionKey=_c71486106-FDE9-6793-86C1-F2F09EE3A3B7_k957A6571-2363-2B11-B728-1C773E120696

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Official Correspondent Information

Contact Name: David Gartner
Company: FDA
Address: 10993 New Hampshire Ave.
Silver Spring, MARYLAND, 20993, UNITED STATES
Telephone: 111-1111111
Fax:
E-mail: david.gartner@fda.hhs.gov

Device Listings > EDIT

Listing Number	Premarket Submission Number/Type	Product Codes	Device Name	Activities
New Listing	Exempt	EJX	ANCHOR, PREFORMED	Manufacture Medical Device*

Certification Statement

By clicking the Submit button I certify that the registration and listing information for this medical device facility as shown on this page is true. I understand that the submission of any report that is false or misleading in any material respect is a violation of Section 301(q)(2), (21 U.S.C. 331(q)(2)) and may be a violation of 18 U.S.C 1001.

Important Notice: If you are required to pay the establishment registration user fee, you must visit the [FDA User Fee website](#) and pay for your facility prior to registering. If you are required to pay the fee and have not yet received your Payment Confirmation Number (PCN), you will not be able to register your facility and will need to return and re-enter all information for the facility.

Who Must Pay: A facility that is required to register that manufactures a device for itself or another party,

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If you have already registered for the current fiscal year, you do not need to provide your Payment Identification Number (PIN) and PCN again.

< CANCEL - RETURN to MAIN MENU

> SUBMIT

Register Your Facility

Enter Payment Confirmation Number

Get Help ?

Enter your Payment Identification Number (PIN) and Payment Confirmation Number (PCN) for each registration shown below.

The PIN is a 8-digit number beginning with the number 5. The PCN is an 8-digit number beginning with the two character fiscal year - for 2012, the PCN begins with "12".

You must have a separate PCN for each registration shown. If you have not yet paid your annual registration user fee, you must visit the [FDA User Fee website](#) and pay for each registered facility prior to completing registration. If you have paid for your registration(s) and do not have your PIN and PCN, you can display your numbers by visiting the [FDA User Fee website](#)

Sample PIN - PCN:50000000-12000000

Registration Number	Address	PIN	PCN
New registration being created	FDA 10993 New Hampshire Ave., Silver Spring, Maryland UNITED STATES	<input type="text"/>	<input type="text"/>

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> SUBMIT