

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

- » Edit Account Profile
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Welcome to the FDA Industry Systems.
You are logged in to your account for company FDA

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

Low Acid Canned Food

Other FDA Systems

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Device Registration and Listing Module System - Windows Internet Explorer

https://www.access.fda.gov/drlm/mainMenu1.htm;jsessionid=0aaa516730d90fa58b94b9444a0f8beca2e215eef01b.e3qRa3qKb30Qe34TaNaTbN4Ka41ynknvrklOlQzNp65Inl

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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](#)

Register a New Facility - Windows Internet Explorer

https://www.access.fda.gov/drlm/drlm.htm?_flowExecutionKey=_c71486106-FDE9-6793-86C1-F2F09EE3A3B7_k40D07BF0-B3B9-4DBC-3588-96F5785E1BD3

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DRLM

Device Registration & Listing Module



FURLS HOME
DRLM HOME

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.

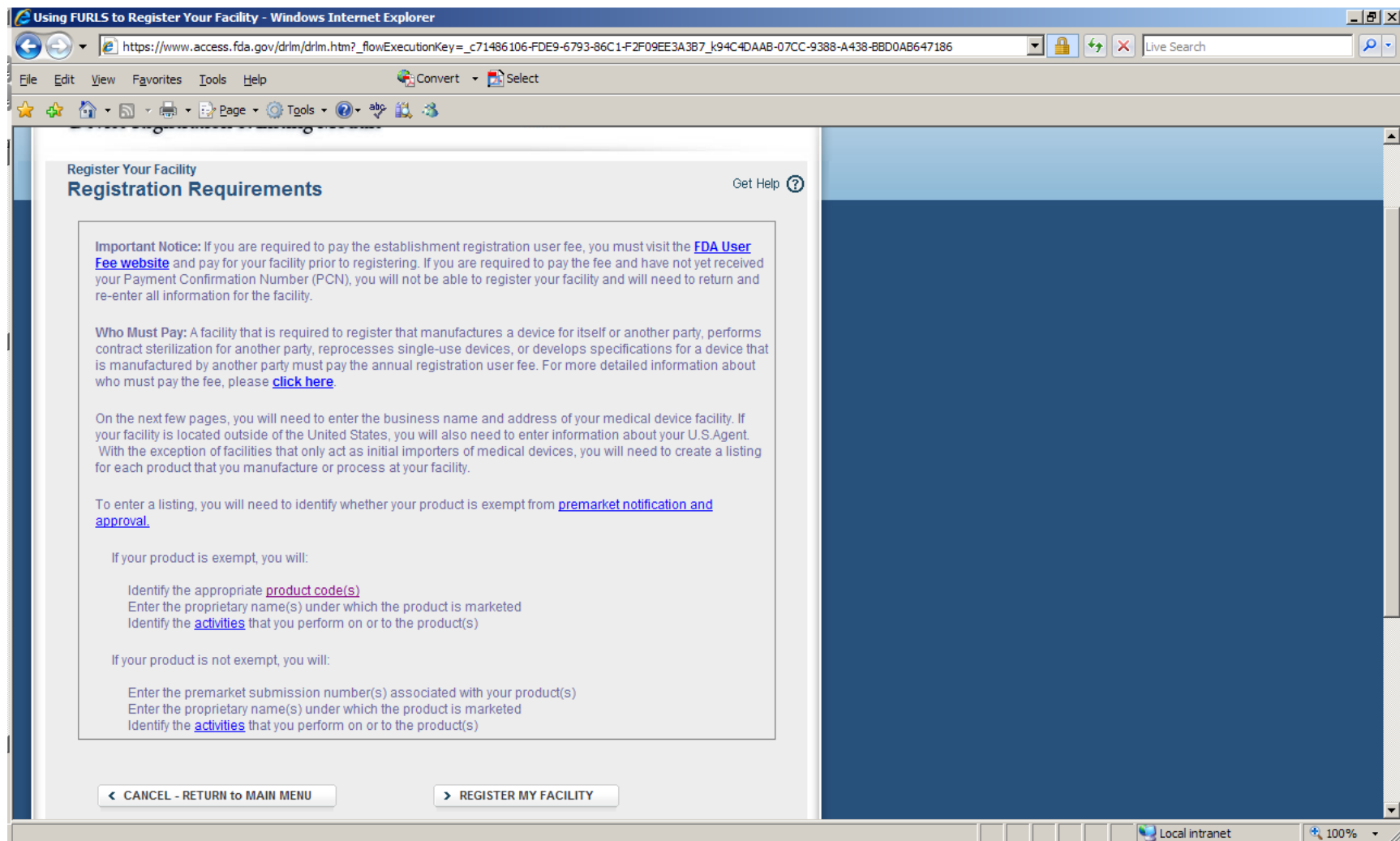
If you do not have a Registration Number or Owner Operator Number, click No Existing Registration or OO Number.

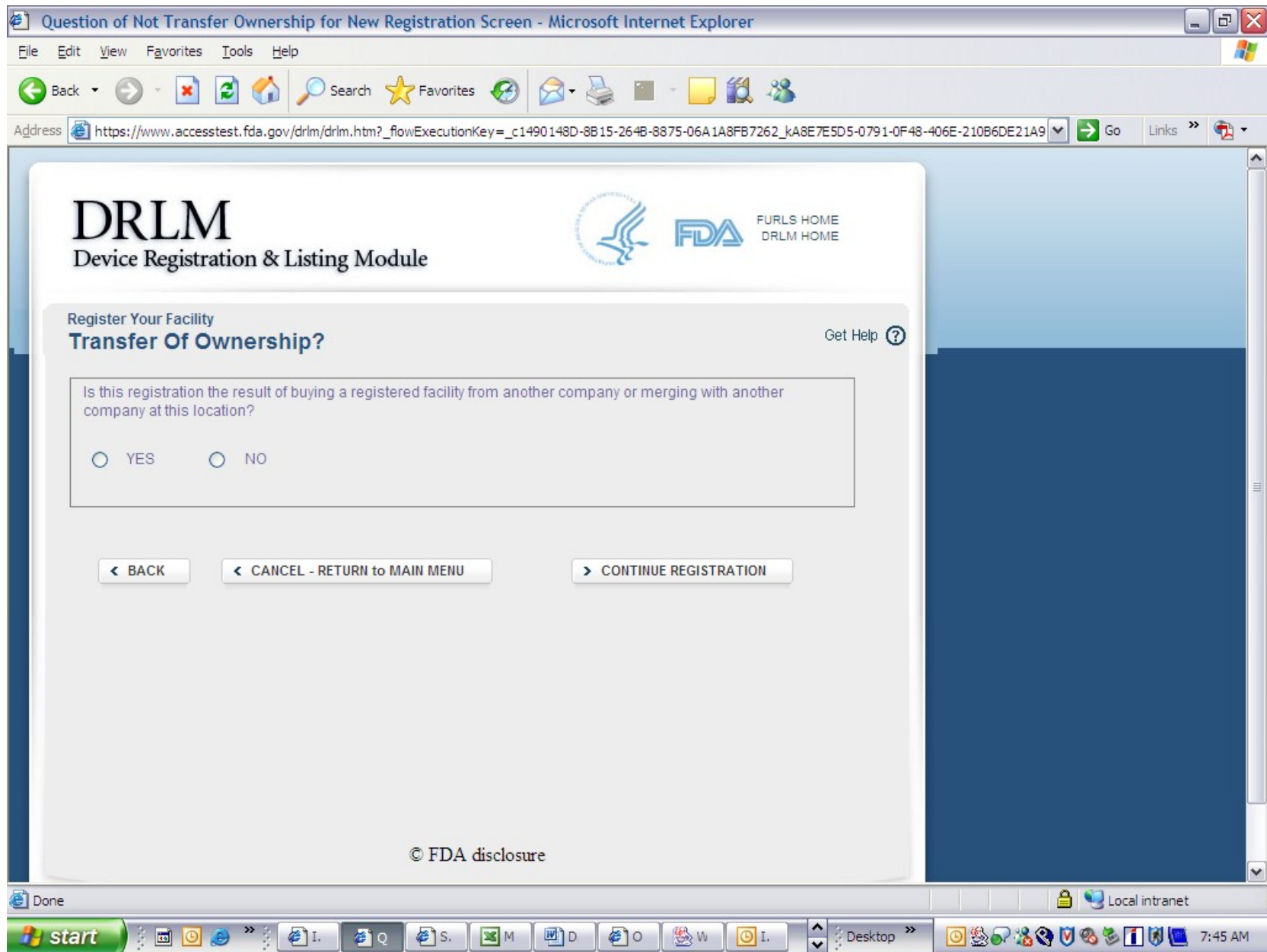
Registration Number OR Owner Operator Number

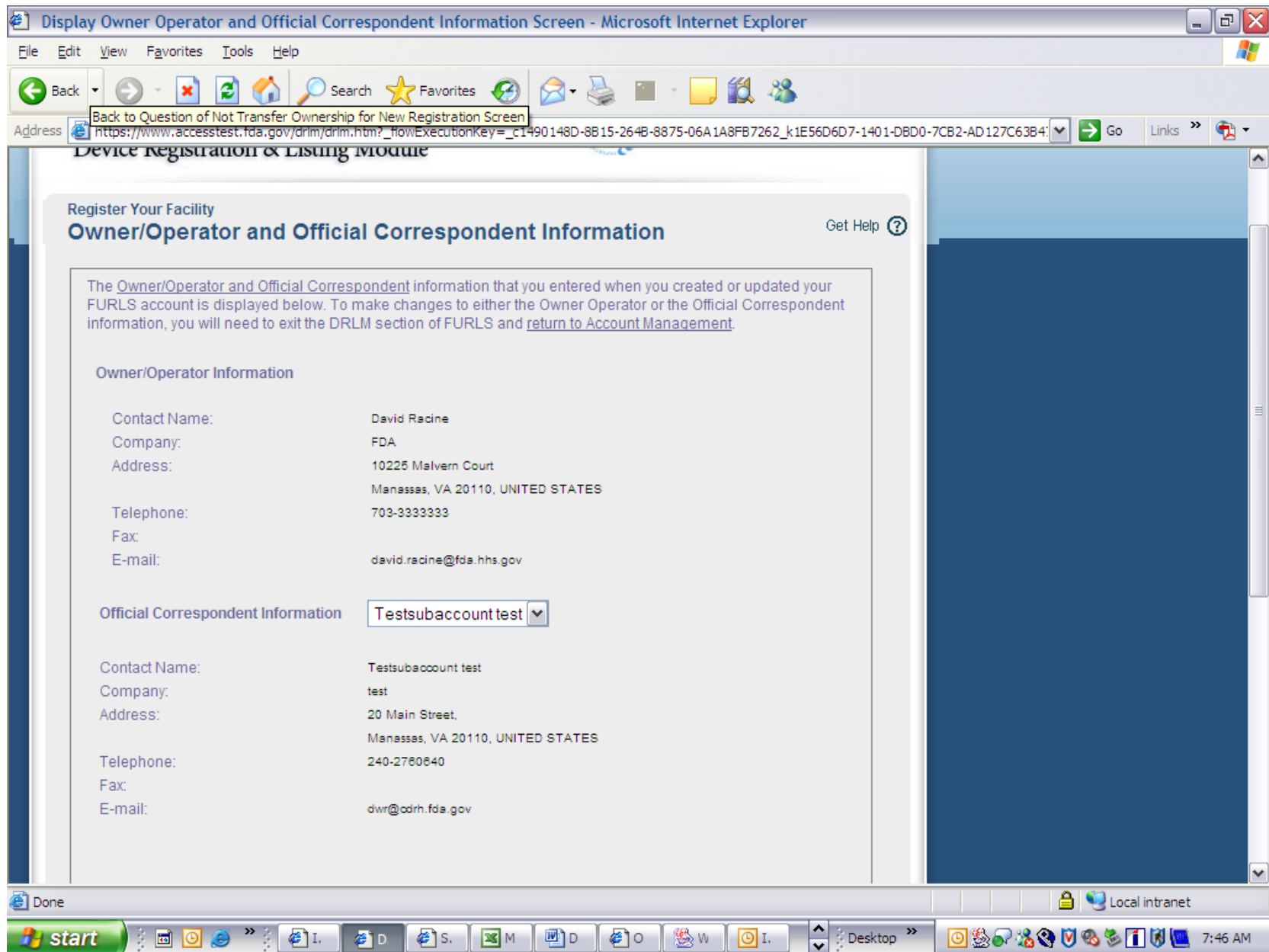
If an establishment at this address has previously been registered with FDA as a device facility, but you do not know your Registration Number or Owner Operator Number, please send an email to reglist@cdrh.fda.gov for assistance. Do not create a new registration if a medical device facility has ever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

< CANCEL - RETURN to MAIN MENU > SEARCH > NO EXISTING REGISTRATION OR OO NUMBER

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Facility Information Screen - Microsoft Internet Explorer

File Edit View Favorites Tools Help

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Address https://www.access.fda.gov/drlm/drlm.htm?_flowExecutionKey=_c1490148D-8B15-264B-8875-06A1A8FB7262_k5E511CC1-CF34-BDF5-49D1-8B20A7F096C Go Links

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: 703 Phone Number: 3333333 Extension:

Fax: Area/City Code: Fax Number:

Facility URL:

Other Business Trade Name(s): > remove

> Add More Trade Names:

Done Local intranet

start Desktop 7:47 AM

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



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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display owner operator listings - Microsoft Internet Explorer

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Address https://www.access.gpo.gov/drlm/drlm.htm?_flowExecutionKey=_c1490148D-8815-264B-8875-06A1A8FB7262_k7F79D6C2-0C4D-4C77-9CB9-5D56A188D9

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.

☐	Listing Number	Listing Status	Premarket Submission Number/Type	Product Code(s)	Device Name	Registration Numbers
☐	D004788	Active	K010680	CAF	NEBULIZER (DIRECT PATIENT INTERFACE)	Not Yet Assigned.
☐	D004789	Active	K904717	CAF	NEBULIZER (DIRECT PATIENT INTERFACE)	Not Yet Assigned.

[< BACK](#) [CANCEL - RETURN TO MAIN MENU](#)

[ADD NEW PRODUCT](#) [ADD SELECTED PRODUCTS TO THIS FACILITY](#)

Done Local intranet

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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

File Edit View Favorites Tools Help

Convert Select

Register Your Facility

Enter Product Number

Get Help ?

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

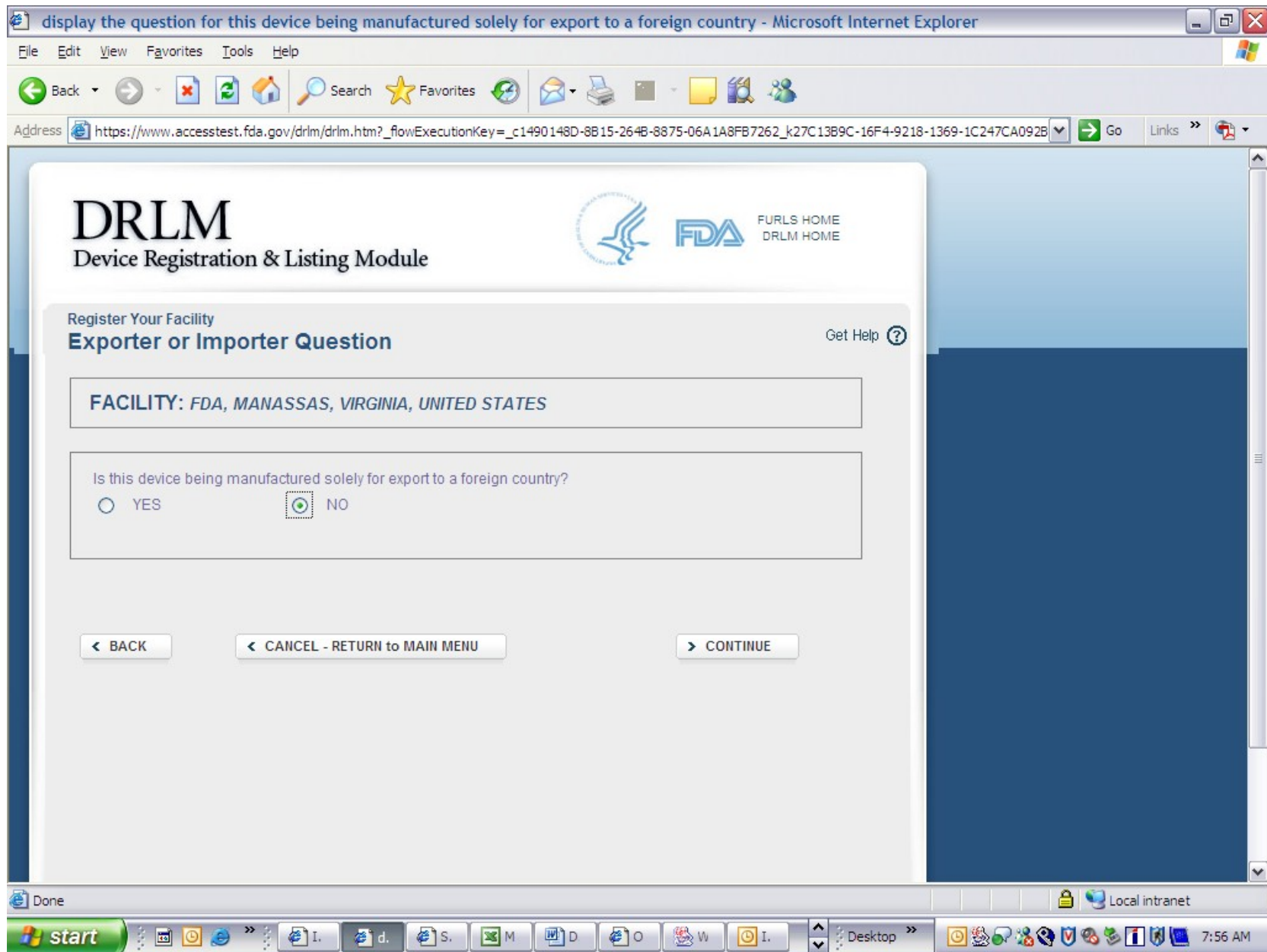
If you believe the product you are listing falls under enforcement discretion or preamendment, please contact the CDRH Registration and Listing Helpdesk at reglist@cdrh.fda.gov.

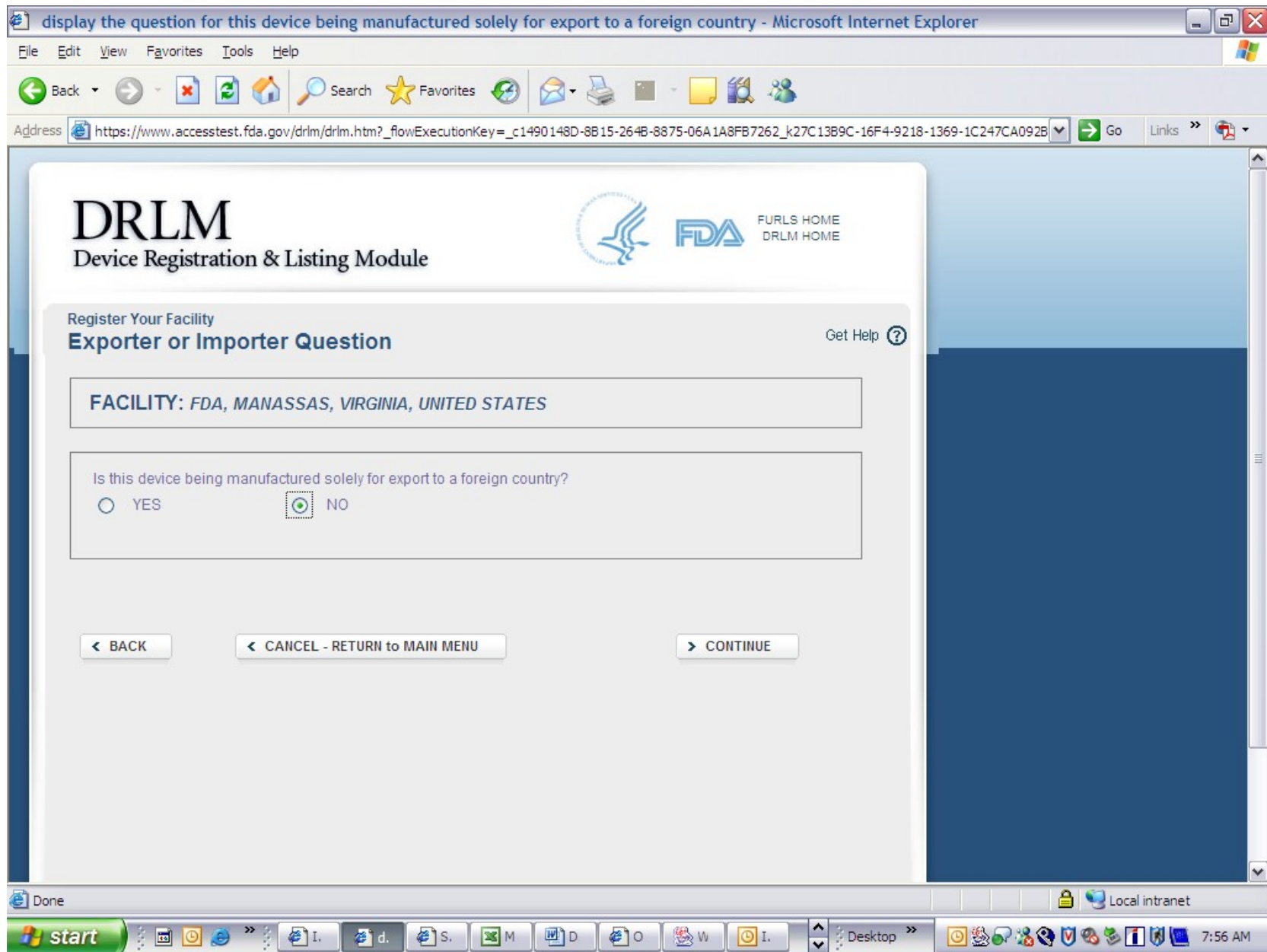
If your device is exempt from FDA premarket notification requirements, leave the box empty and click "Continue".

Enter the Premarket Submission Number:

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

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display product code list - Microsoft Internet Explorer

File Edit View Favorites Tools Help

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Address https://www.access.gpo.gov/drug/drug.htm?_flowExecutionKey=_c1490148D-8B15-264B-8875-06A1A8FB7262_k8EA62976-27FF-2659-BEA5-BAD3B8B81B3 Go Links

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
☒	DENTAL	EJX	ANCHOR, PREFORMED	1	510(k) exempt
☐	GENERAL AND PLASTIC SURGERY	NEH	ANCHOR, FASCIAL	2	510(k)
☐	ORTHOPEDIC	NWN	Kit, laparoscopic, bone anchor, urethropexy	2	510(k)
☐	ORTHOPEDIC	NOV	ANCHOR, SUTURE, BONE FIXATION, METALLIC	2	510(k)

☐ None of the above. Request new product code.

Done Search Results - Microsoft Internet Explorer Local intranet

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display product code list - Microsoft Internet Explorer

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Address https://www.access.gpo.gov/drug/drug.htm?_flowExecutionKey=_c1490148D-8B15-264B-8875-06A1A8FB7262_k8EA62976-27FF-2659-BEA5-BAD3B8B81B3 Go Links

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
☒	DENTAL	EJX	ANCHOR, PREFORMED	1	510(k) exempt
☐	GENERAL AND PLASTIC SURGERY	NEH	ANCHOR, FASCIAL	2	510(k)
☐	ORTHOPEDIC	NWN	Kit, laparoscopic, bone anchor, urethropexy	2	510(k)
☐	ORTHOPEDIC	NOV	ANCHOR, SUTURE, BONE FIXATION, METALLIC	2	510(k)

☐ None of the above. Request new product code.

Done Search Results - Microsoft Internet Explorer Local intranet

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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

File Edit View Favorites Tools Help

Convert Select

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DRLM

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

< BACK

< CANCEL - RETURN to MAIN MENU

> CONTINUE

facility listing summary - Microsoft Internet Explorer

File Edit View Favorites Tools Help

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Address https://www.access.gpo.gov/drms/drms.htm?_flowExecutionKey=_c1490148D-8815-264B-8875-06A1A8FB7262_k541438A2-FE35-F49E-A153-2C3EB917A5D Go Links

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
☐	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](#)

Done Local intranet

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DRLM

Device Registration & Listing Module



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[DRLM HOME](#)

[Register Your Facility](#)

Registration Review

Get Help 

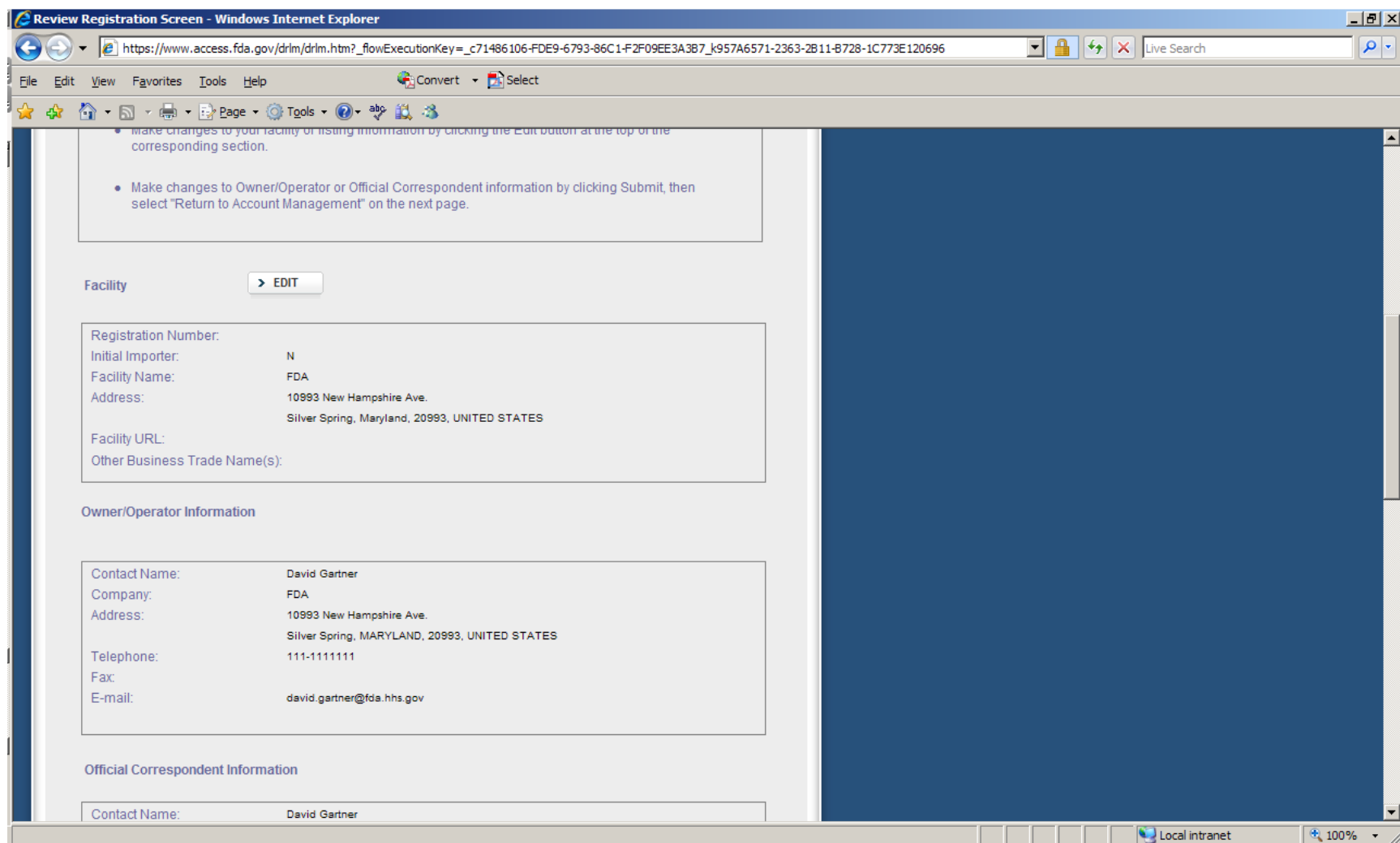
FACILITY: FDA, SILVER SPRING, MARYLAND, UNITED STATES

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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



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

Live Search

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PageTools🔗📄📄📄

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.

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

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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.

< CANCEL - RETURN to MAIN MENU

> SUBMIT

Enter Payment Confirmation Number - Windows Internet Explorer

https://www.access.fda.gov/drlm/drlm.htm?_flowExecutionKey=_c71486106-FDE9-6793-86C1-F2F09EE3A3B7_kE39009AF-0296-DA8E-E0E4-3A1D4A0A6761

File Edit View Favorites Tools Help Convert Select

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		

< BACK

> SUBMIT

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