Device Registration and Listing Module

Form Number: FDA 3673

OMB Number: 0910-0625

OMB Expiration Date: xx/xx/20xx

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 0.50 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,

Three White Flint North, 10A-12M

11601 Landsdown St.

North Bethesda, MD 20852

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 Office of Management and Budget (OMB) control number.


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FDA Industry Systems Home | Browser Requirements | FAQ | Help Desk
FDA Industry Systems
System Status
Help Desk
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.
NEW USERS
LOGIN
Local intranet
100%

Create New Account

See Instructions

See Tutorials

Help Desk

Existing account holders, enter your account ID and password.

Account ID:

Password: Forgot your 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

Login


FDA Industry Systems - Accounts Management - Windows Internet Explorer
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U.S. Food and Drug Administration
Department of Health and Human Services
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FDA Industry Systems Home | Browser Requirements | FAQ | Help Desk | logout
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 fda15659
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
Prior Notice
FDA Industry Systems Home | Browser Requirements | FAQ | Help Desk | logout
Done
Local intranet
100%


Device Registration and Listing Module System - Windows Internet Explorer
https://www.access.fda.gov/drlm/mainMenu1.htm;jsessionid=0aaa516730d90fa58b94b9444a0f8beca2e215eef01b.e3qRa3qKb30Qe34TaNaTbN4Ka41ynknvrkLOlQzNp65In
Live Search
File Edit View Favorites Tools Help
Convert
Select
Page
Tools
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
Local intranet
100%

Cancel, Deactivate, or Reactivate a Facility Registration

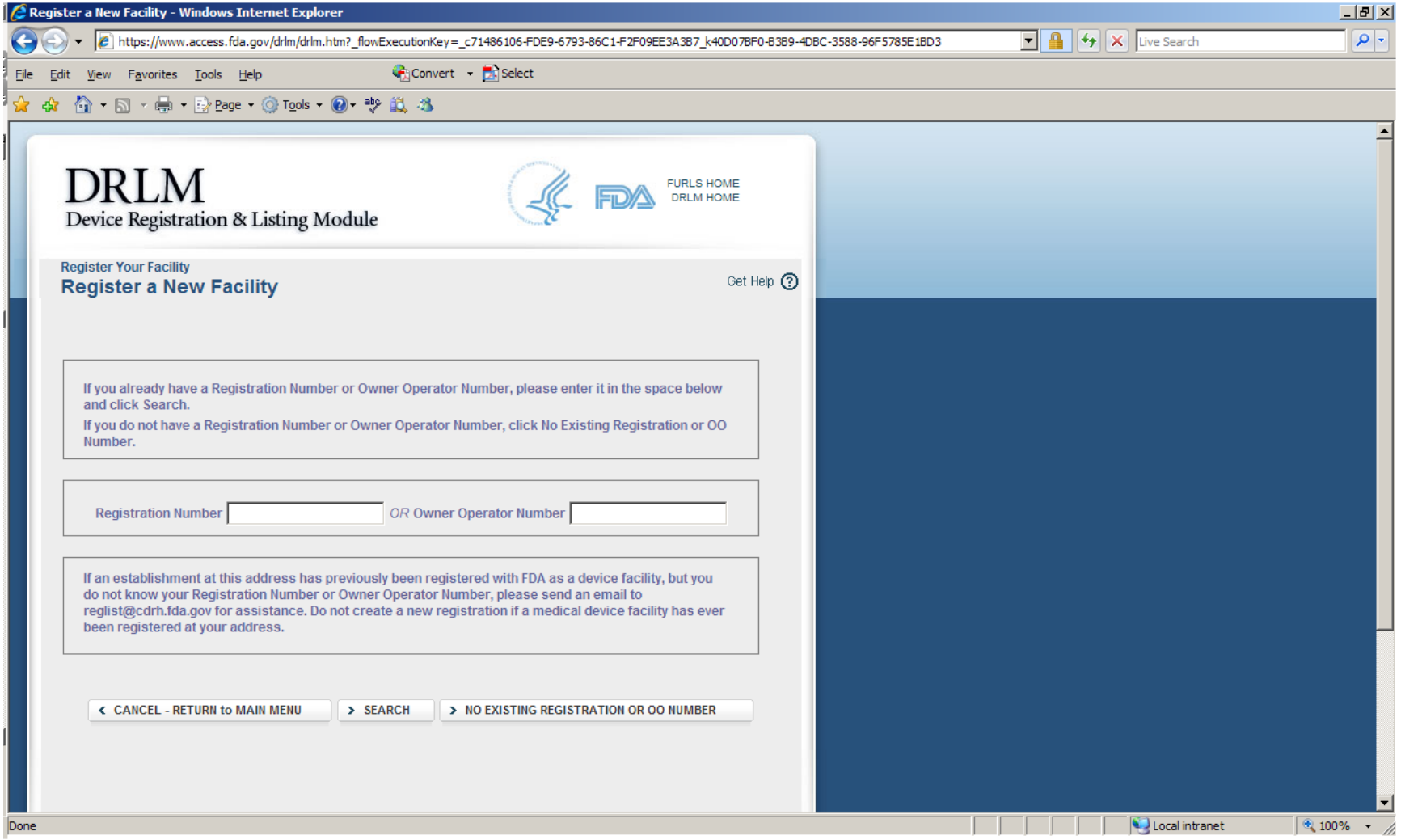
Change the Official Correspondent for a Facility

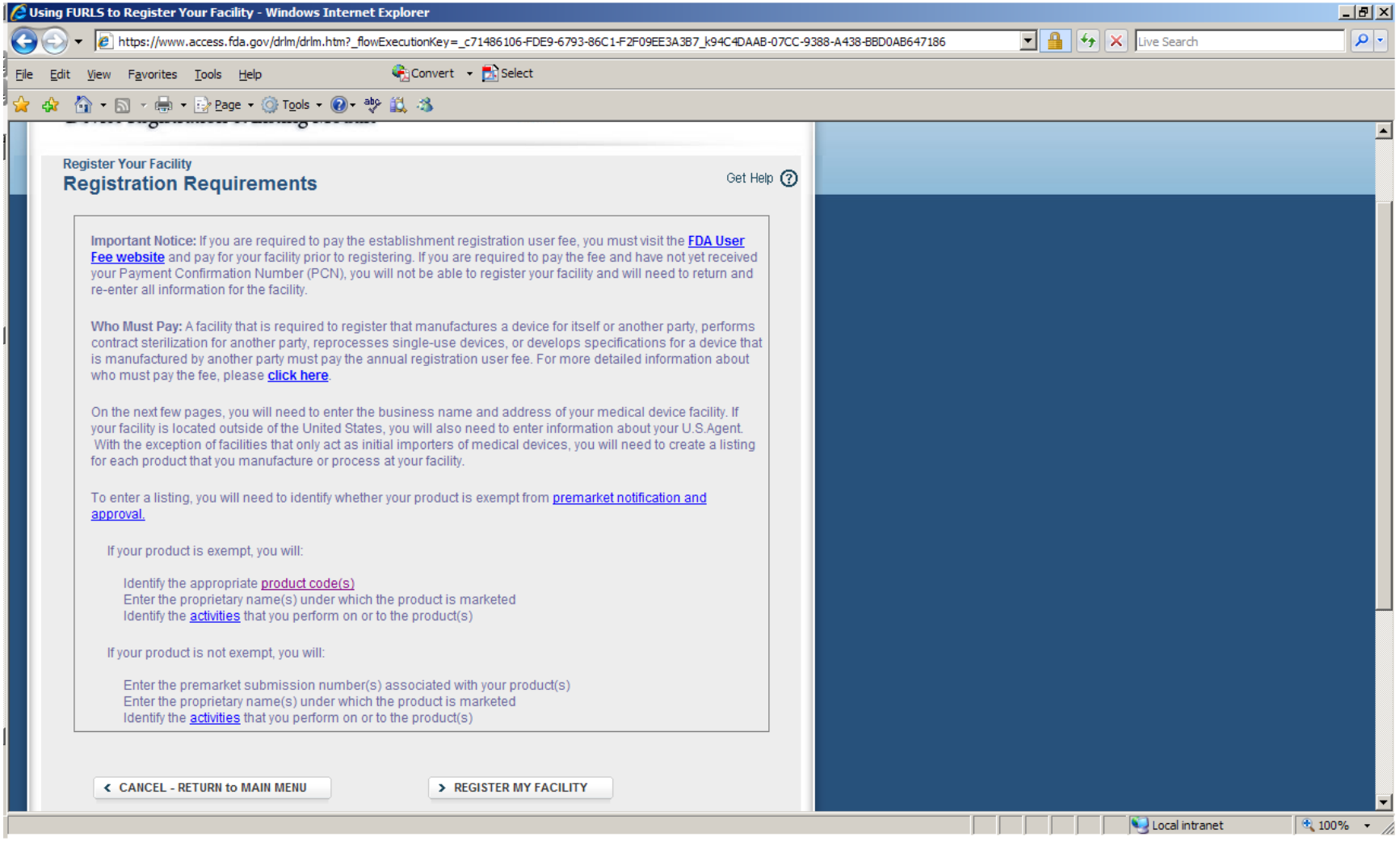
Register a **New** Medical Device Facility

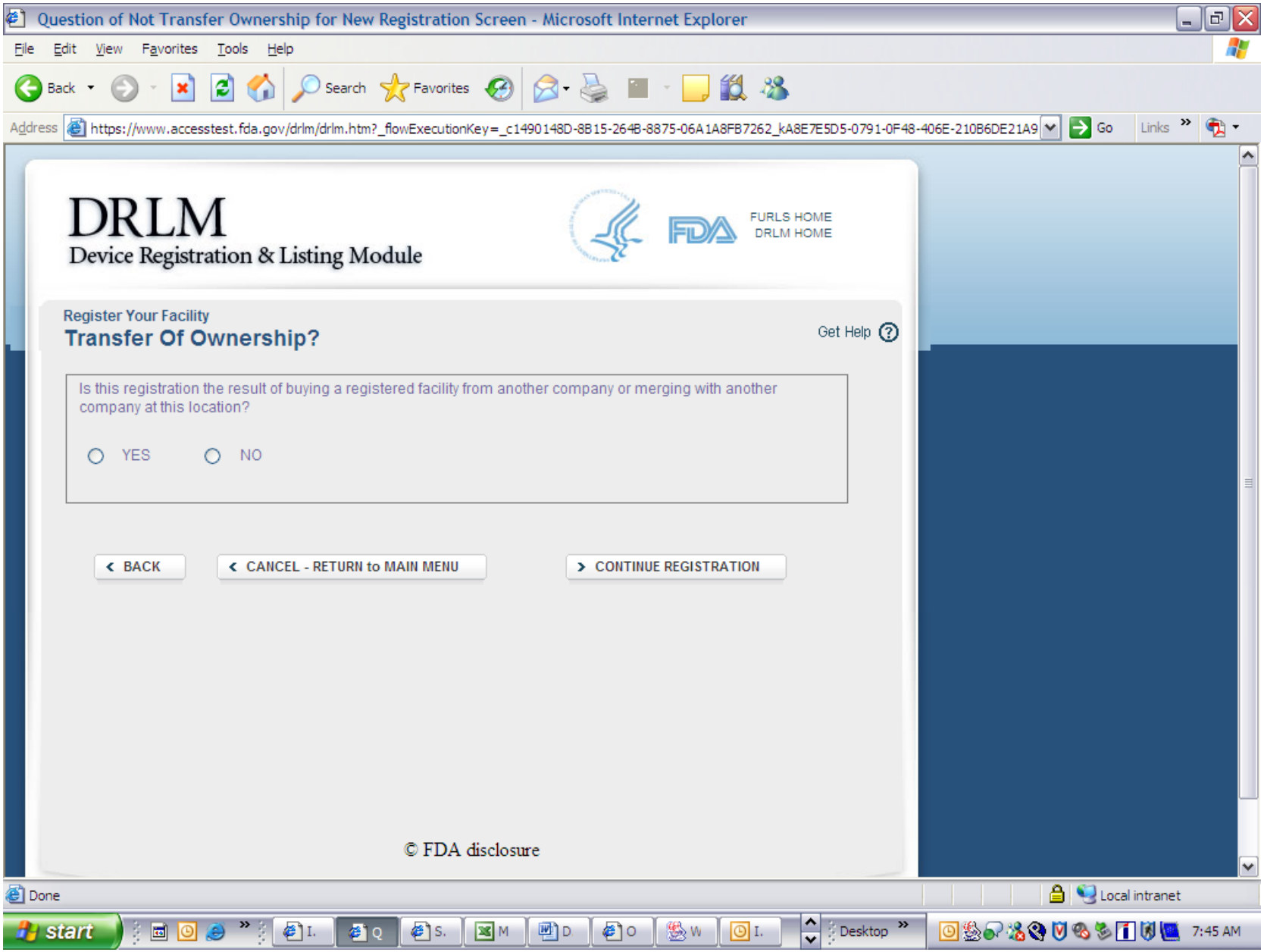
Create Listings for Medical Devices

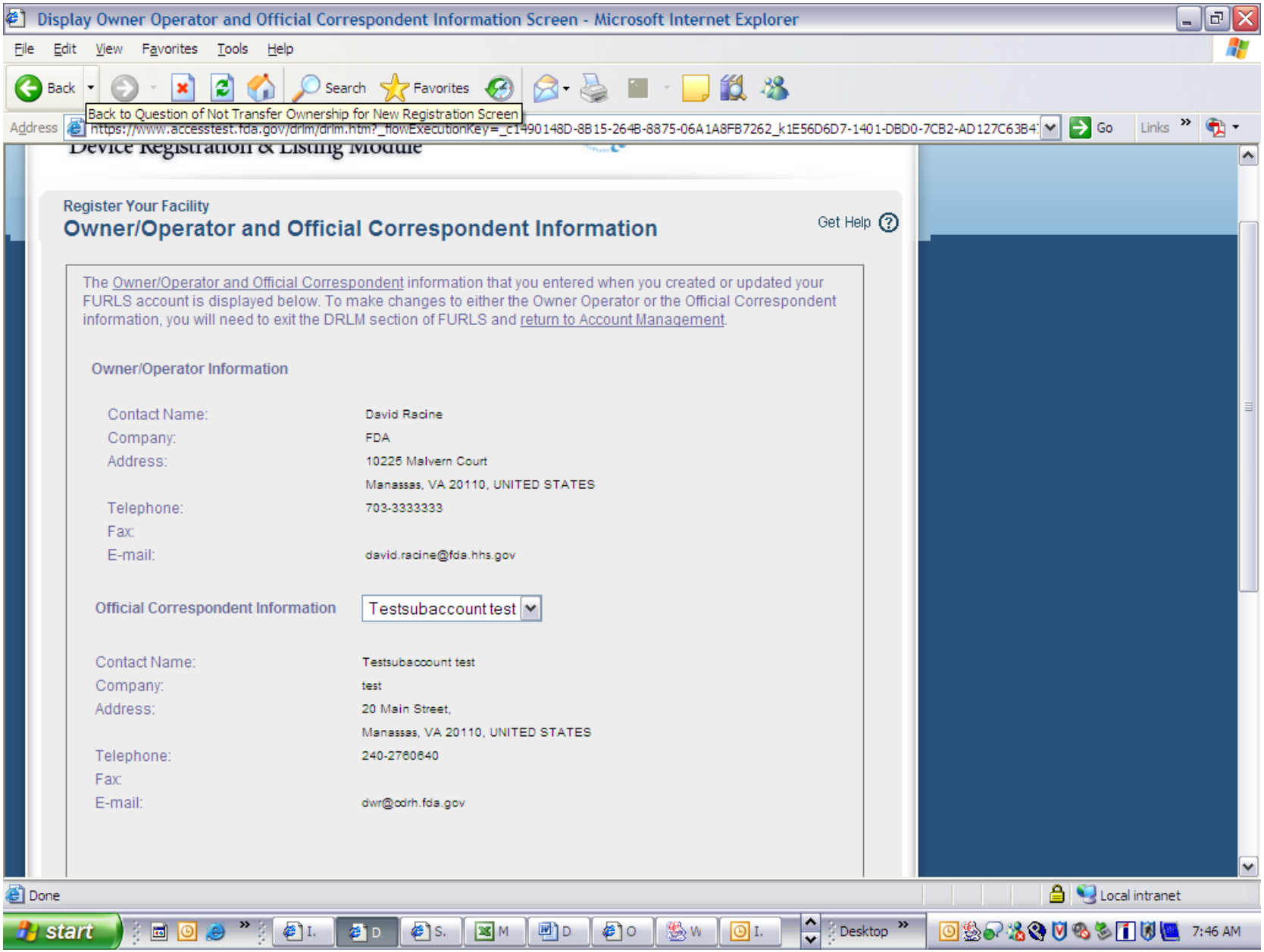
Change, Cancel, or Reactivate Listings

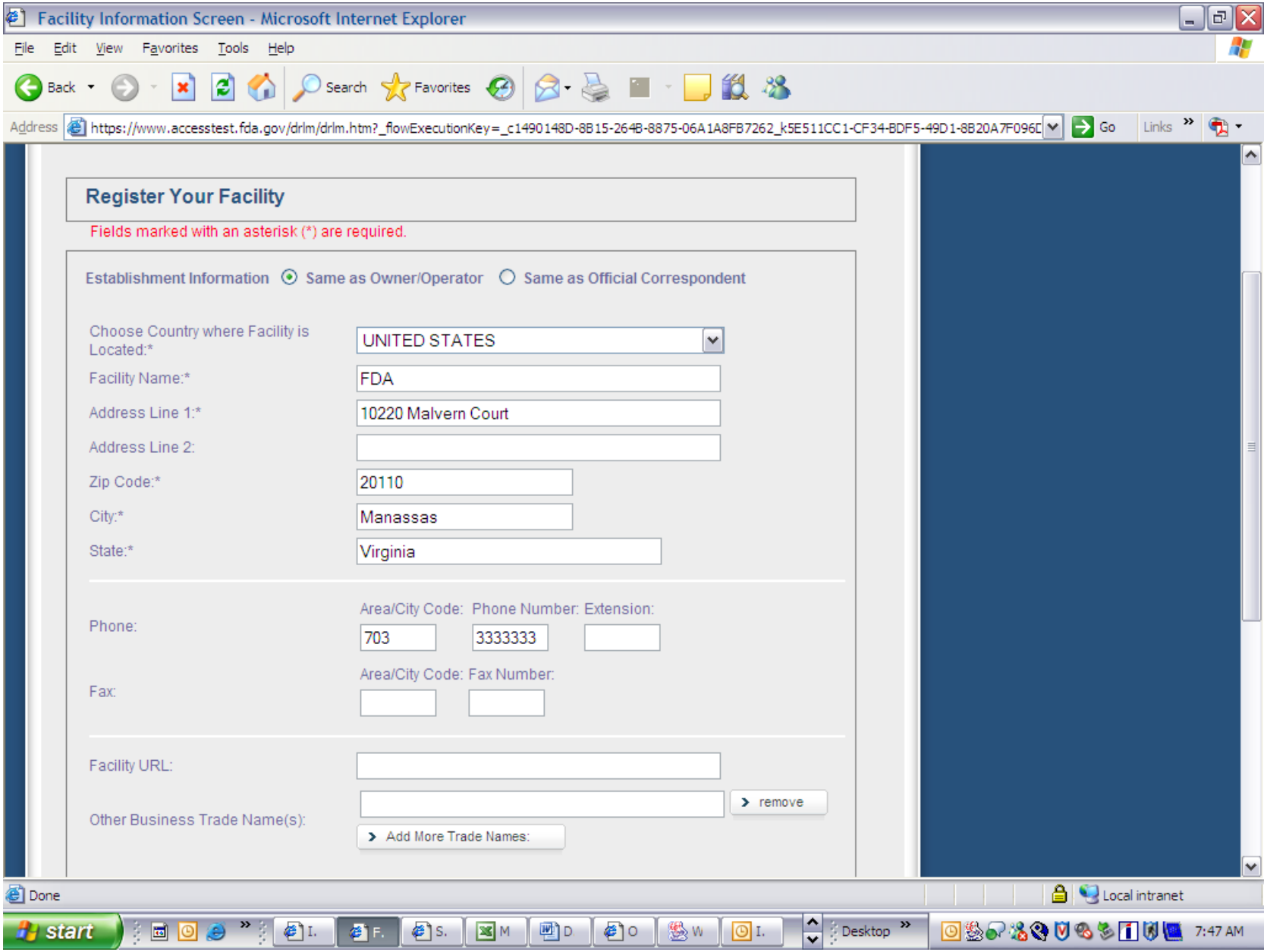
Transfer Ownership of Devices or Facilities

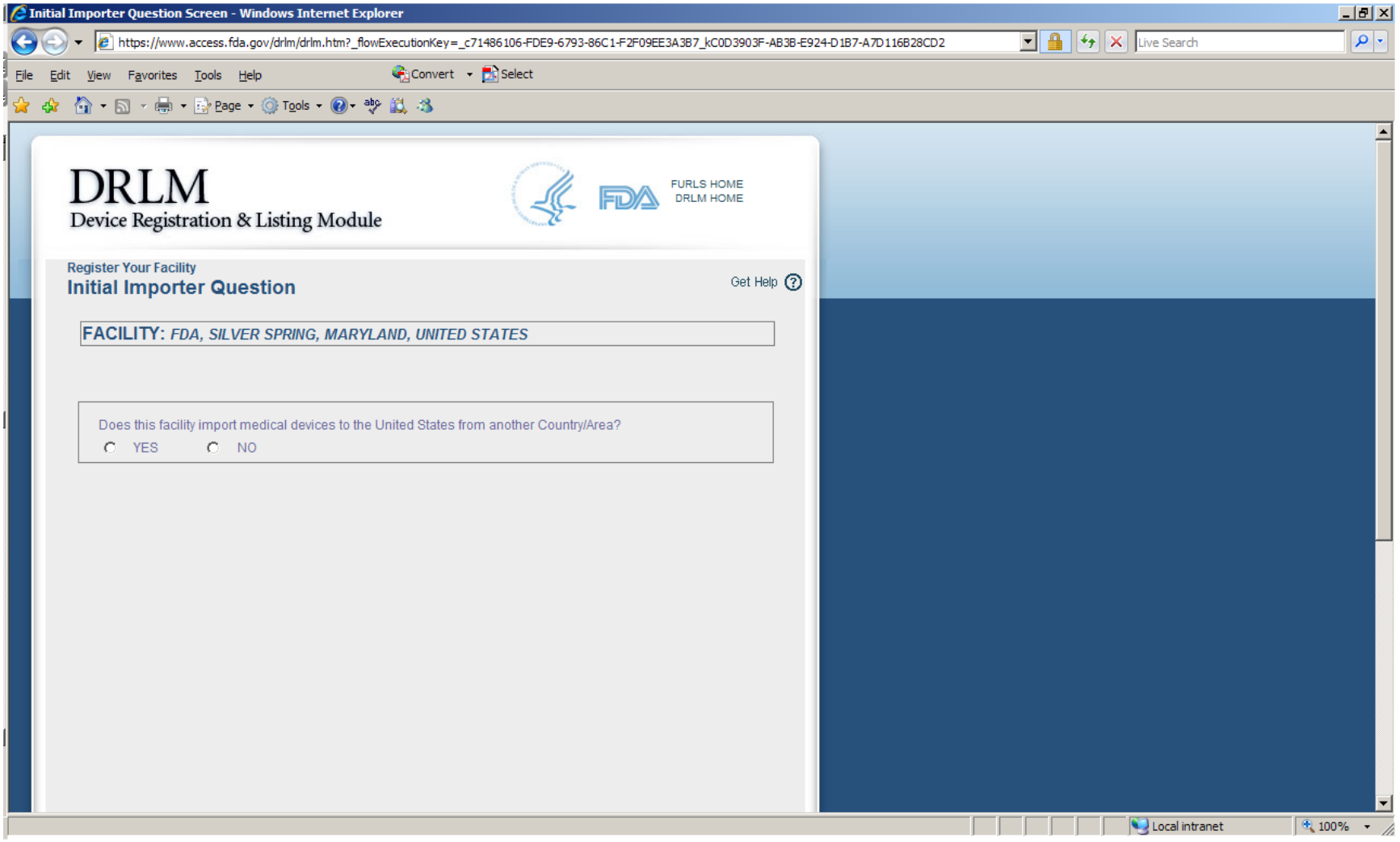

Register a New Facility - Windows Internet Explorer
https://www.access.fda.gov/drlm/drlm.htm?_flowExecutionKey=_c71486106-FDE9-6793-86C1-F2F09EE3A3B7_k40D07BF0-B3B9-4DBC-3588-96F5785E1BD3
Live Search
File Edit View Favorites Tools Help
Convert Select
Page Tools
DRLM
Device Registration & Listing Module
FDA
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
Done
Local intranet
100%

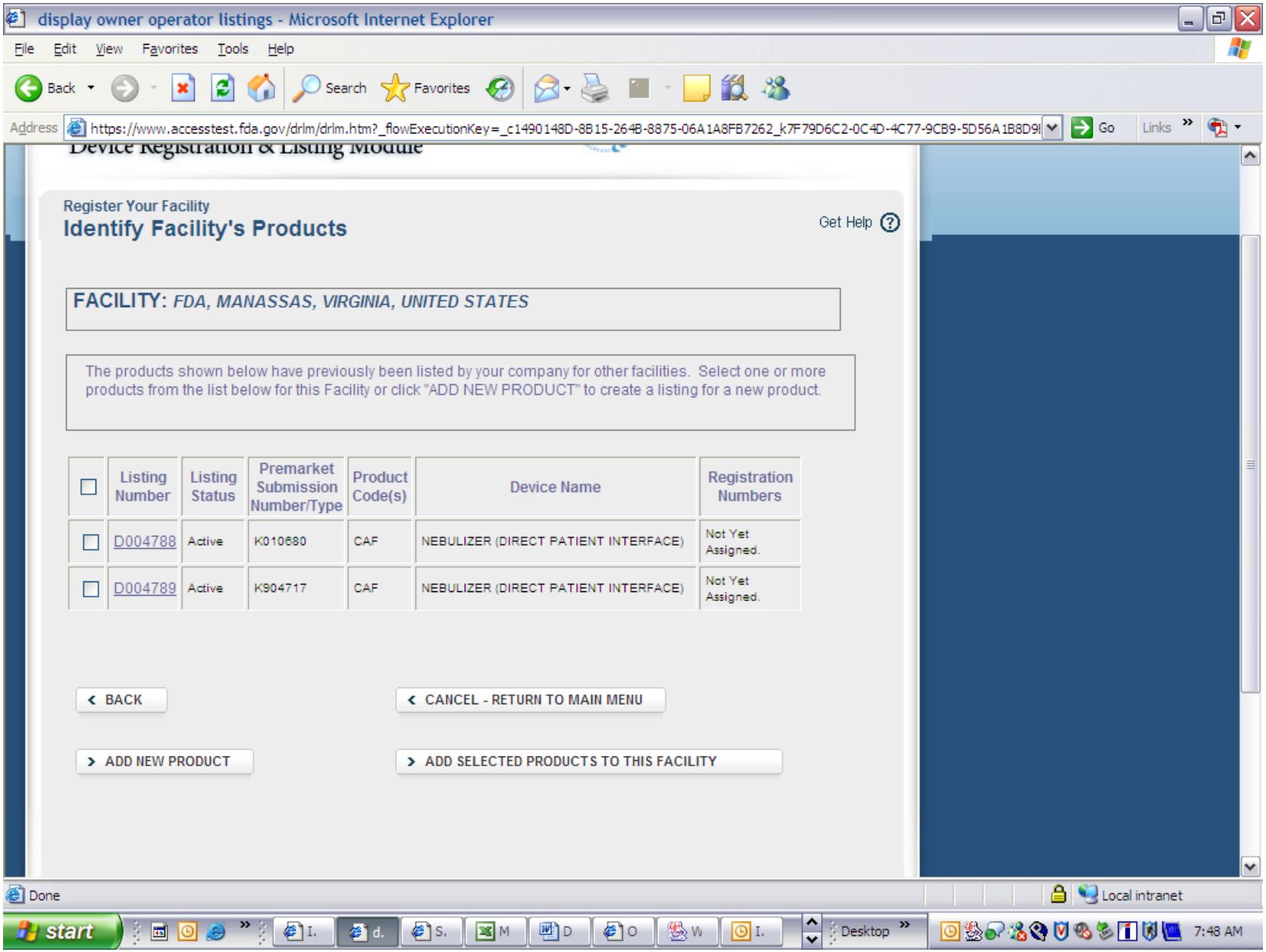

Using FURLS to Register Your Facility - Windows Internet Explorer
https://www.access.fda.gov/drlm/drlm.htm?_flowExecutionKey=_c71486106-FDE9-6793-86C1-F2F09EE3A3B7_k94C4DAAB-07CC-9388-A438-BBD0AB647186
Live Search
File Edit View Favorites Tools Help
Convert Select
Page Tools
Register Your Facility
Registration Requirements
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.
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
Local intranet
100%

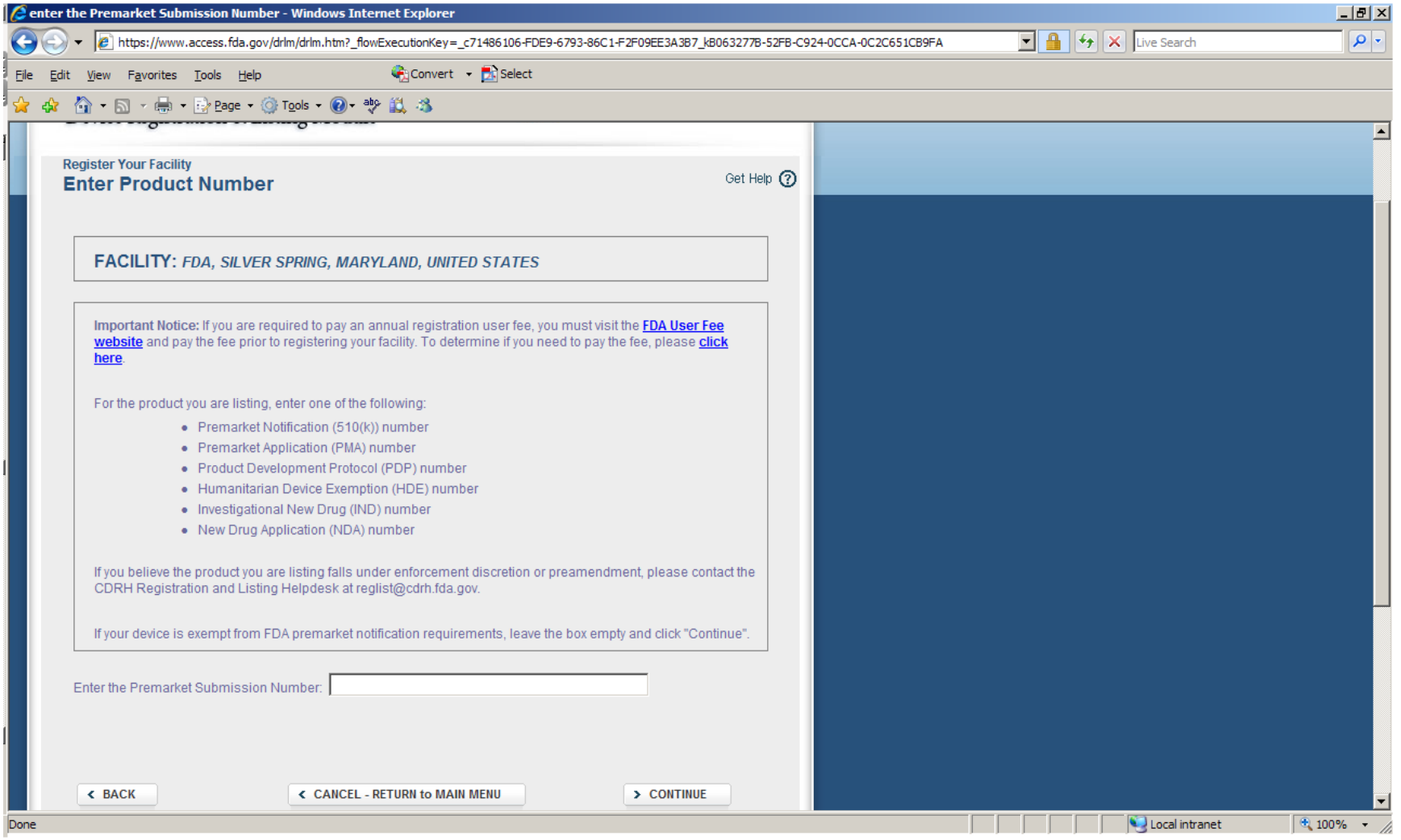

Question of Not Transfer Ownership for New Registration Screen - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back Search Favorites
Address https://www.accesstest.fda.gov/drlm/drlm.htm?_flowExecutionKey=_c1490148D-8B15-264B-8875-06A1A8FB7262_kA8E7E5D5-0791-0F48-406E-210B6DE21A9
Go Links
DRLM
Device Registration & Listing Module
FDA
FURLS HOME
DRLM HOME
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
© FDA disclosure
Done
Local intranet
start
Desktop
7:45 AM

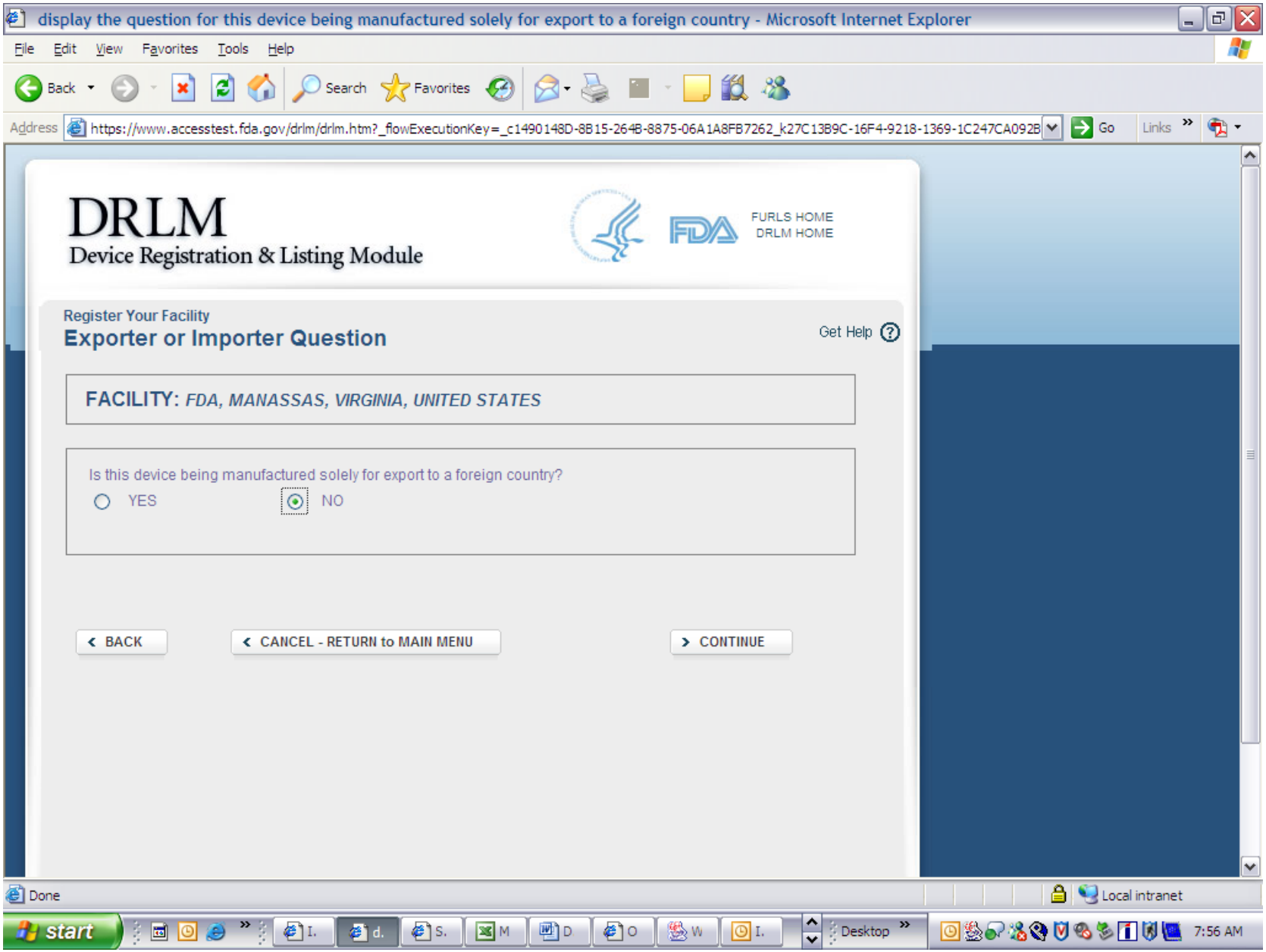

Display Owner Operator and Official Correspondent Information Screen - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back
Search
Favorites
Back to Question of Not Transfer Ownership for New Registration Screen
Address
https://www.accesstest.fda.gov/drlm/drlm.htm?_flowExecutionKey=_c1490148D-8B15-264B-8875-06A1A8FB7262_k1E56D6D7-1401-DBD0-7CB2-AD127C63B4
Go
Links
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: 240-2760640
Fax:
E-mail: dwr@odrh.fda.gov
Done
Local intranet
start
Desktop
7:46 AM

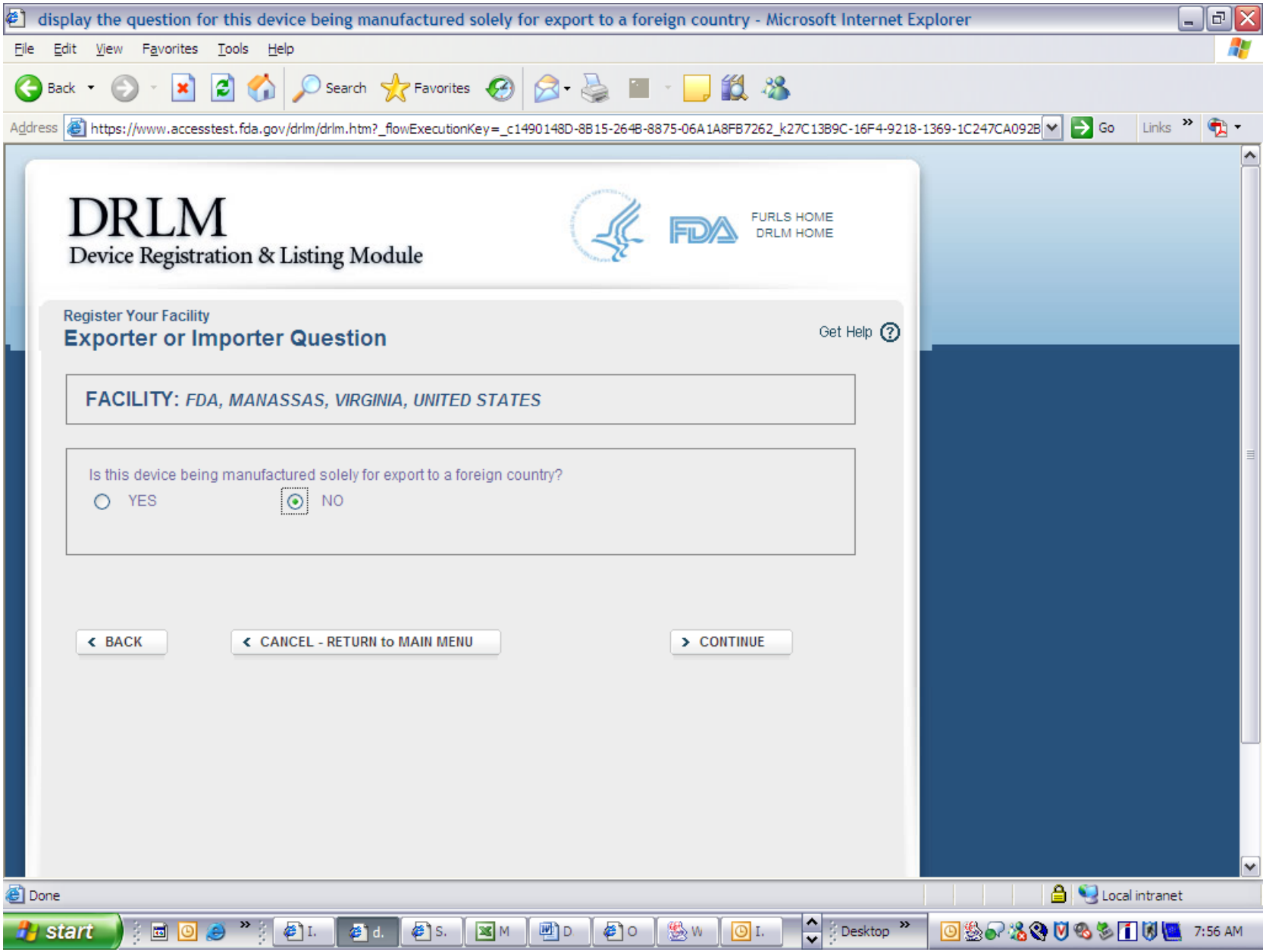

Facility Information Screen - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back Search Favorites
Address https://www.accesstest.fda.gov/drlm/drlm.htm?_flowExecutionKey=_c1490148D-8B15-264B-8875-06A1A8FB7262_k5E511CC1-CF34-BDF5-49D1-8B20A7F096D
Go Links
Register Your Facility
Fields 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:
Phone Number:
Extension:
703
3333333
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

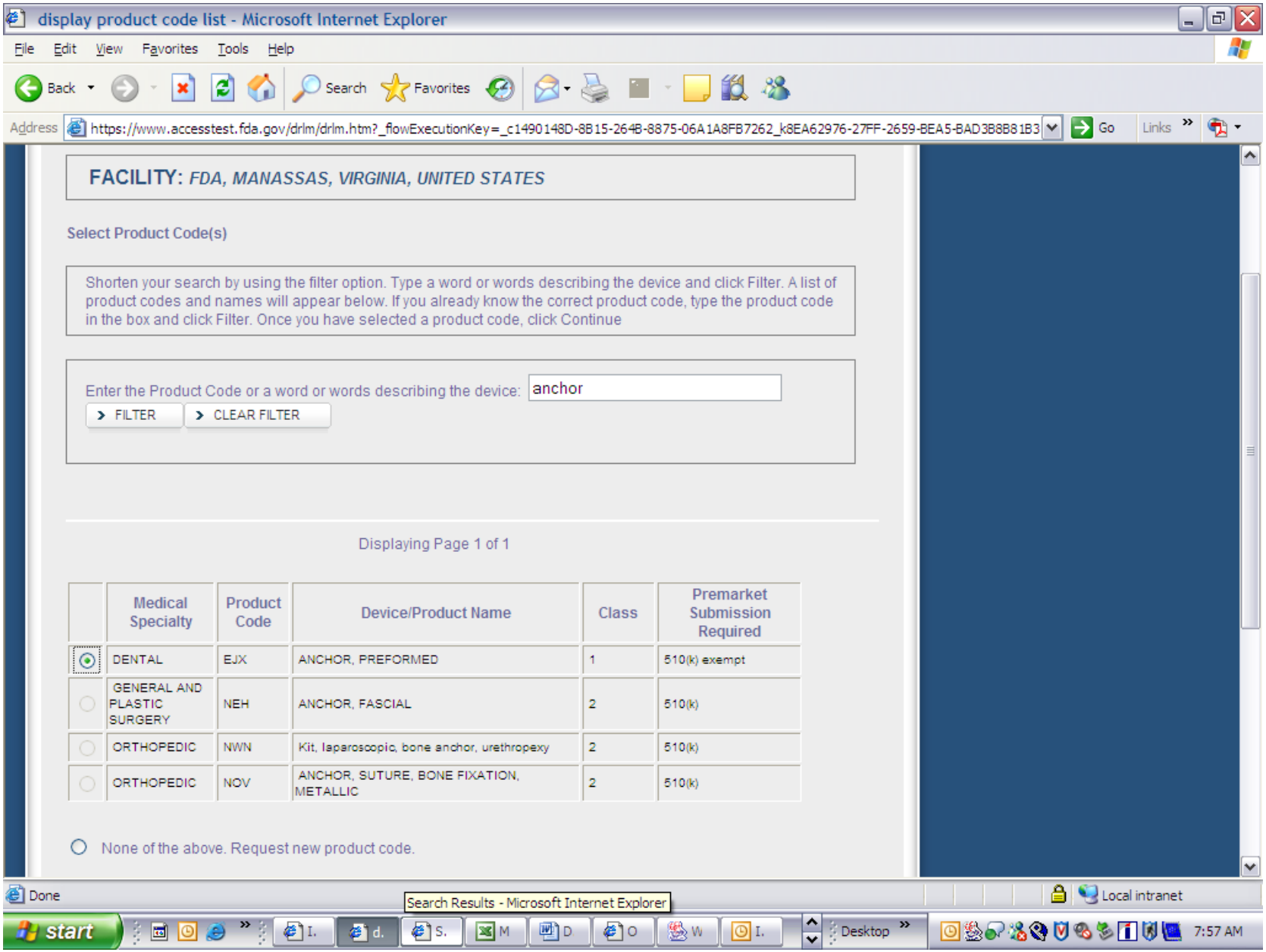

Initial Importer Question Screen - Windows Internet Explorer
https://www.access.fda.gov/drlm/drlm.htm?_flowExecutionKey=_c71486106-FDE9-6793-86C1-F2F09EE3A3B7_kC0D3903F-AB3B-E924-D1B7-A7D116B28CD2
Live Search
File Edit View Favorites Tools Help
Convert Select
Page Tools
DRLM
Device Registration & Listing 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
Local intranet
100%

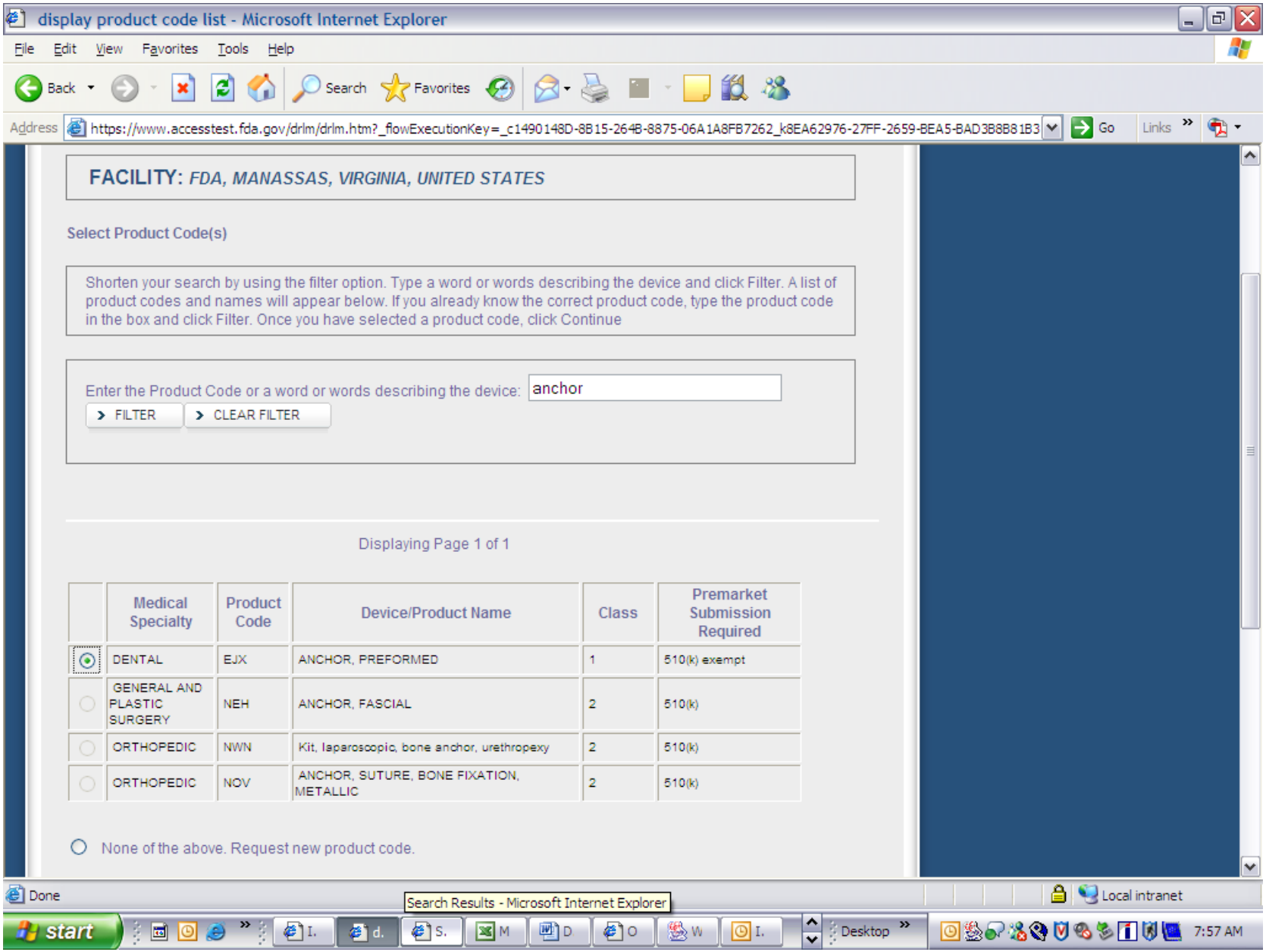

display owner operator listings - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back Search Favorites
Address https://www.accesstest.fda.gov/drlm/drlm.htm?_flowExecutionKey=_c1490148D-8B15-264B-8875-06A1A8FB7262_k7F79D6C2-0C4D-4C77-9CB9-5D56A1B8D9
Go Links
Device Registration & Listing 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
start
Desktop
7:48 AM


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
Live Search
File Edit View Favorites Tools Help
Convert Select
Page Tools
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
Done
Local intranet
100%

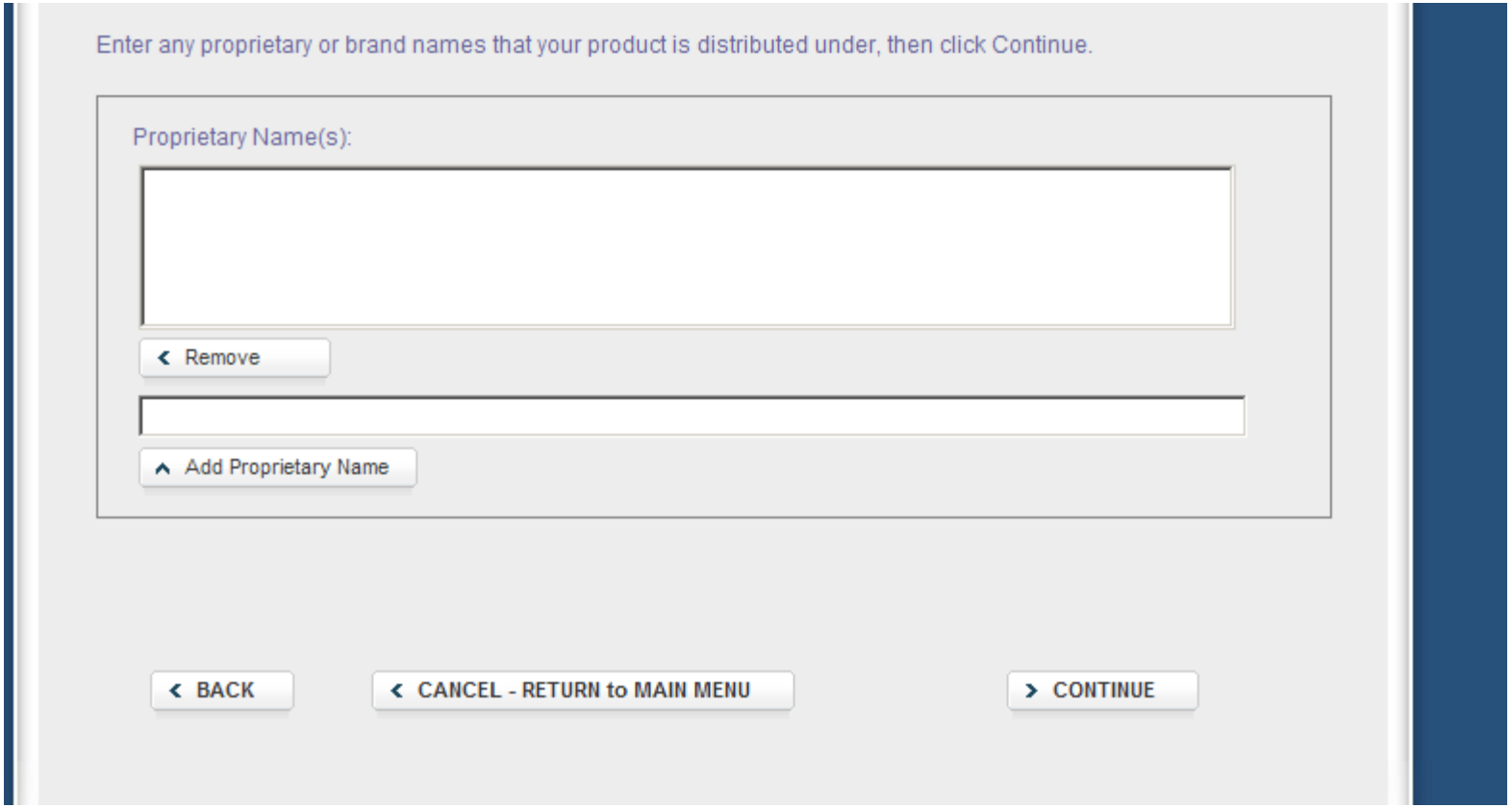

display the question for this device being manufactured solely for export to a foreign country - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back Search Favorites
Address https://www.accesstest.fda.gov/drlm/drlm.htm?_flowExecutionKey=_c1490148D-8B15-264B-8875-06A1A8FB7262_k27C13B9C-16F4-9218-1369-1C247CA092B
Go Links
DRLM
Device Registration & Listing Module
FDA
FURLS HOME
DRLM HOME
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
Done
Local intranet
start
Desktop
7:56 AM

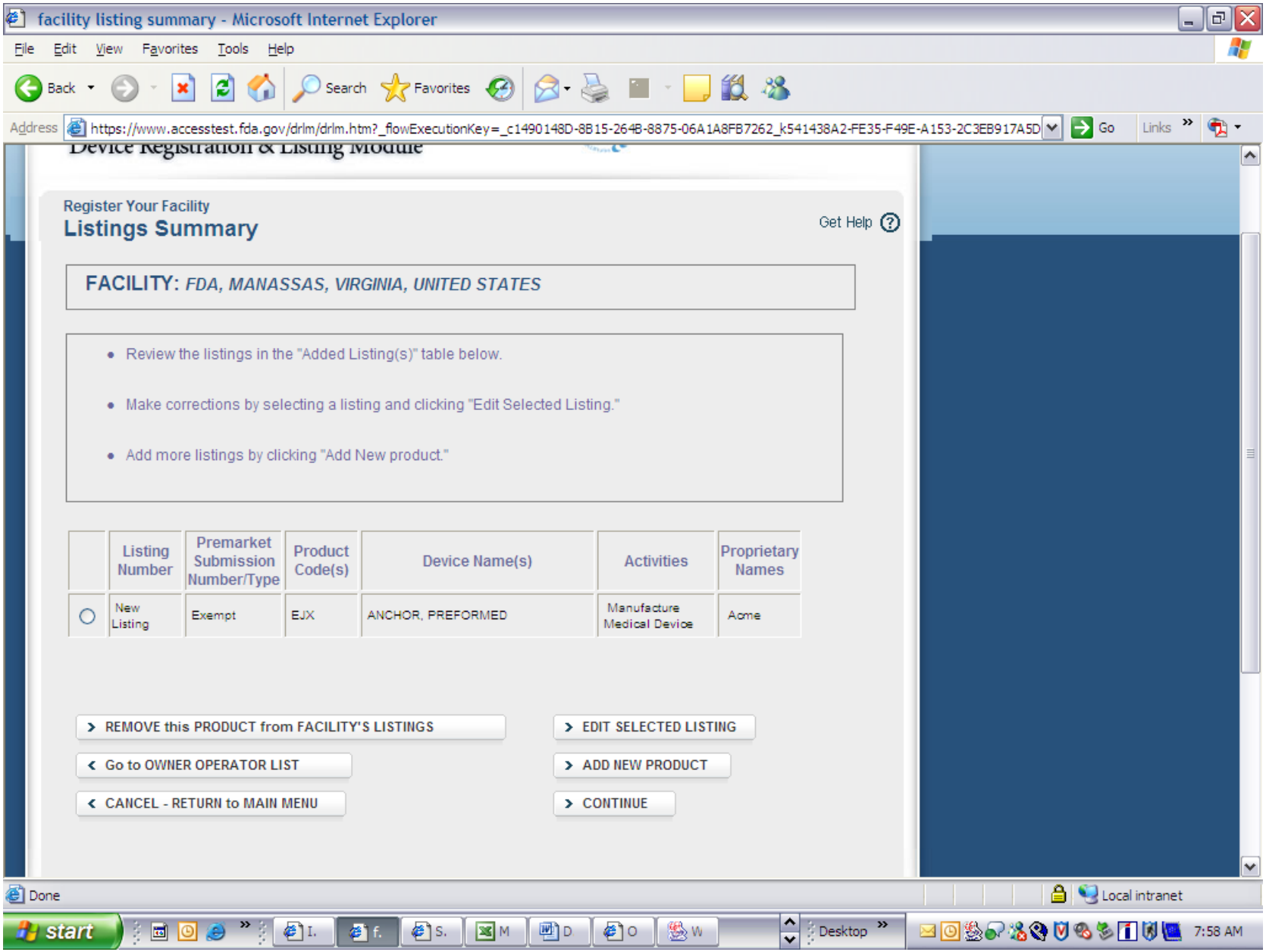

display the question for this device being manufactured solely for export to a foreign country - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back Search Favorites
Address https://www.accesstest.fda.gov/drlm/drlm.htm?_flowExecutionKey=_c1490148D-8B15-264B-8875-06A1A8FB7262_k27C13B9C-16F4-9218-1369-1C247CA092B
Go Links
DRLM
Device Registration & Listing Module
FDA
FURLS HOME
DRLM HOME
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
Done
Local intranet
start
Desktop
7:56 AM


display product code list - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back Search Favorites
Address https://www.accesstest.fda.gov/drlm/drlm.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: anchor
FILTER
CLEAR FILTER
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
start
Desktop
7:57 AM

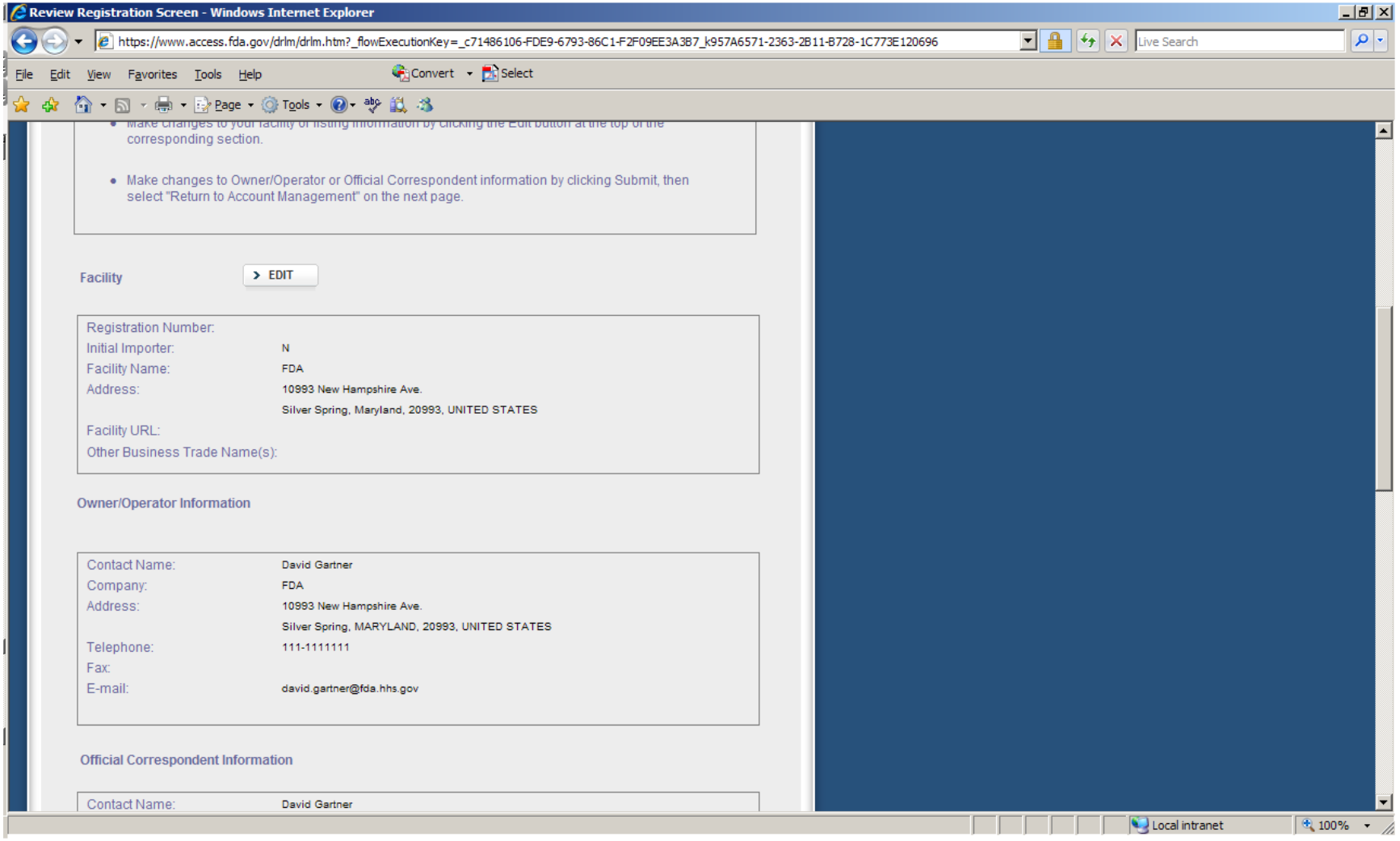

display product code list - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back Search Favorites
Address https://www.accesstest.fda.gov/drlm/drlm.htm?_flowExecutionKey=_c1490148D-8B15-264B-8875-06A1A8FB7262_k8EA62976-27FF-2659-BEA5-BAD3B8B81B3
Go Links
FACILITY: FDA, MANASSAS, VIRGINIA, 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: anchor
FILTER
CLEAR FILTER
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
start
Desktop
7:57 AM

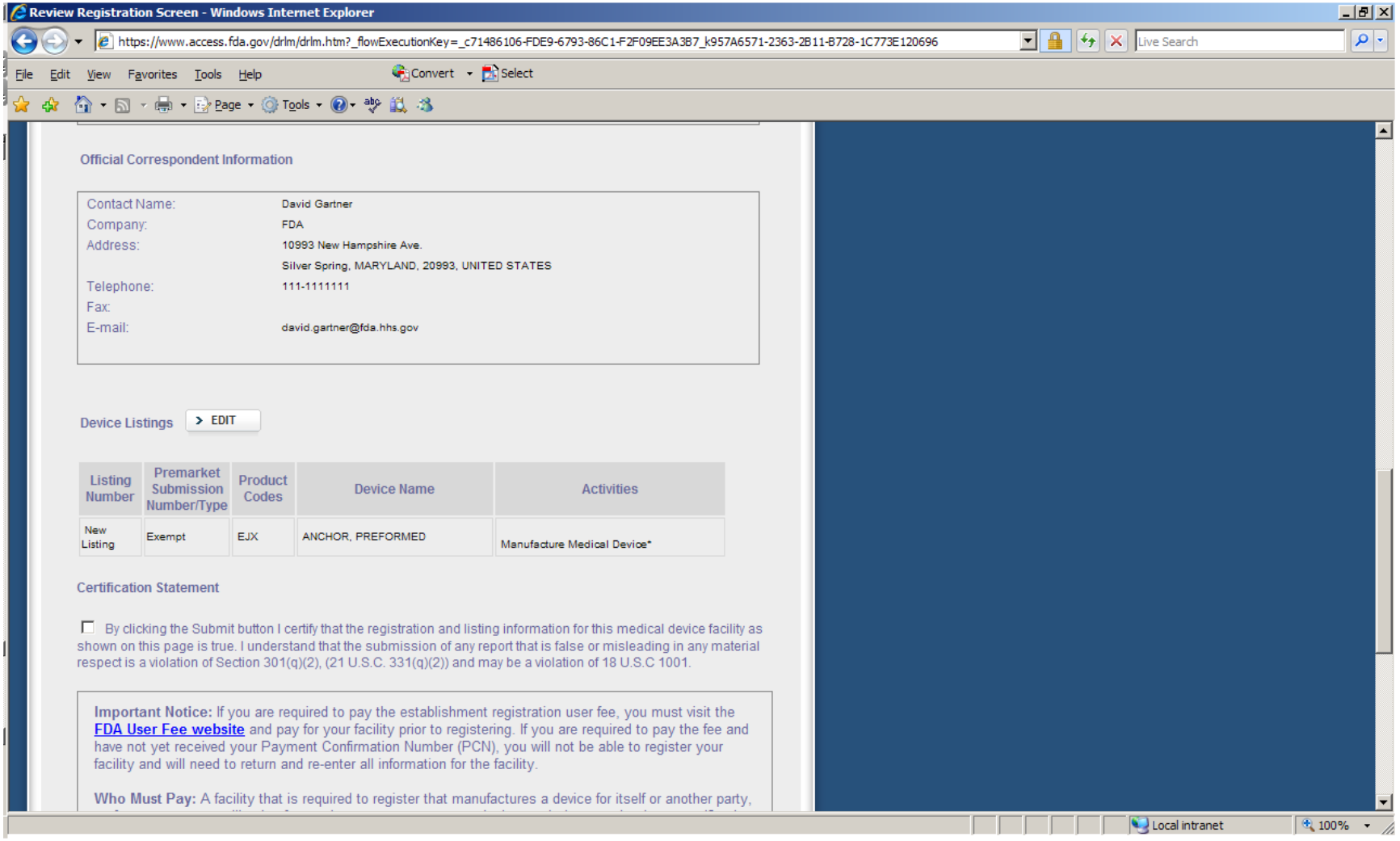

select facility types - Windows Internet Explorer
https://www.access.fda.gov/drlm/drlm.htm?_flowExecutionKey=_c71486106-FDE9-6793-86C1-F2F09EE3A3B7_kB2A950BC-BE6E-1A91-0512-BC0BD94EE447
Live Search
File Edit View Favorites Tools Help
Convert Select
Page Tools
DRLM
Device Registration & Listing Module
FDA
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
Local intranet
100%


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
Back Search Favorites
Address https://www.accesstest.fda.gov/drlm/drlm.htm?_flowExecutionKey=_c1490148D-8B15-264B-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
start
Desktop
7:58 AM


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
Live Search
File Edit View Favorites Tools Help
Convert
Select
Page
Tools
DRLM
Device Registration & Listing Module
FDA
FURLS HOME
DRLM HOME
Register Your Facility
Registration Review
Get Help
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
Done
Local intranet
100%


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
Live Search
File Edit View Favorites Tools Help
Convert Select
Page Tools
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
Local intranet
100%

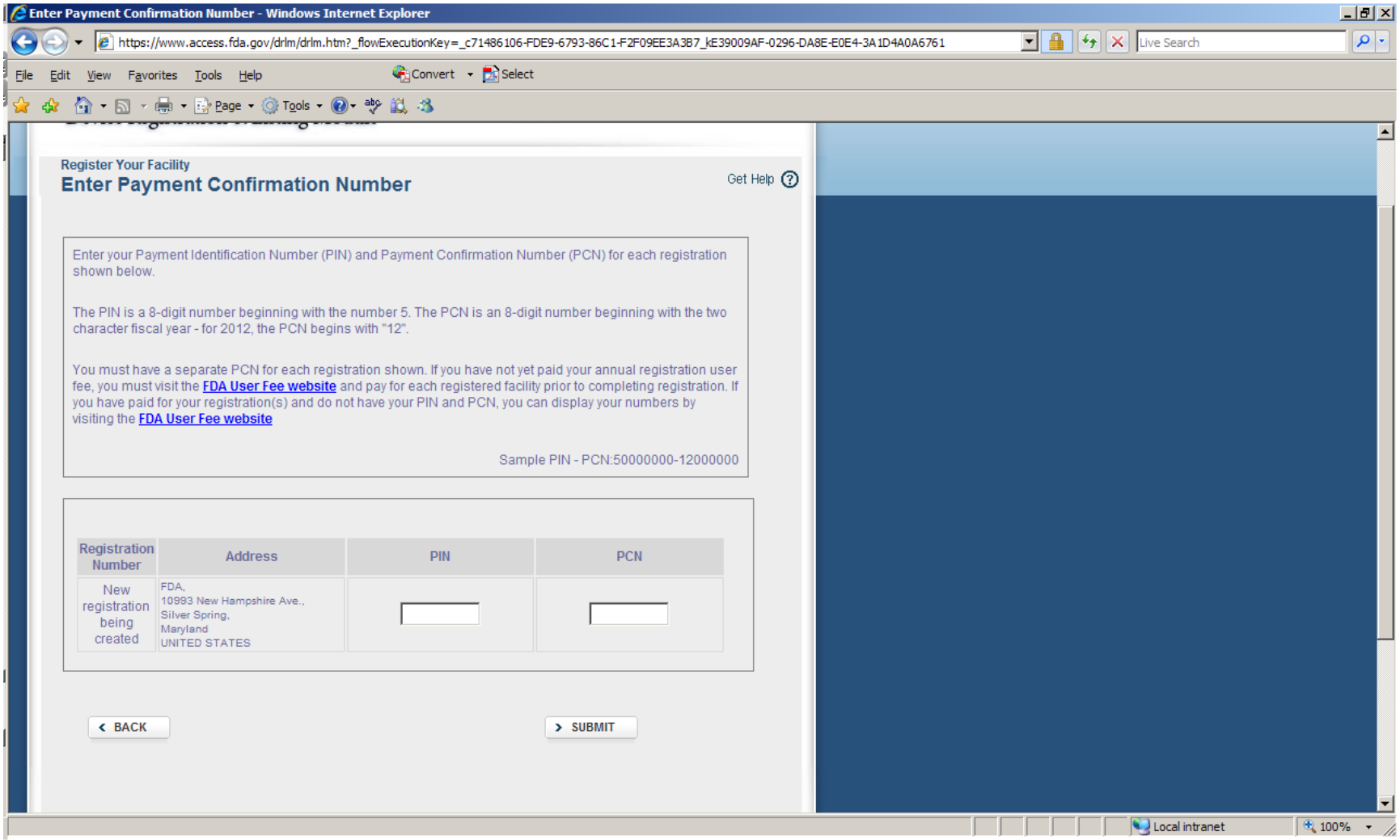

Review Registration Screen - Windows Internet Explorer
https://www.access.fda.gov/drlm/drlm.htm?_flowExecutionKey=_c71486106-FDE9-6793-86C1-F2F09EE3A3B7_k957A6571-2363-2B11-B728-1C773E120696
Live Search
File Edit View Favorites Tools Help
Convert Select
Page Tools
Official Correspondent Information
Contact 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,
Local intranet
100%

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
Live Search
File Edit View Favorites Tools Help
Convert Select
Page Tools
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
Local intranet
100%