Device Registration and Listing Module

Form Number: FDA 3673

OMB Number: 0910- 0625

OMB Expiration Date: 03/31/2012

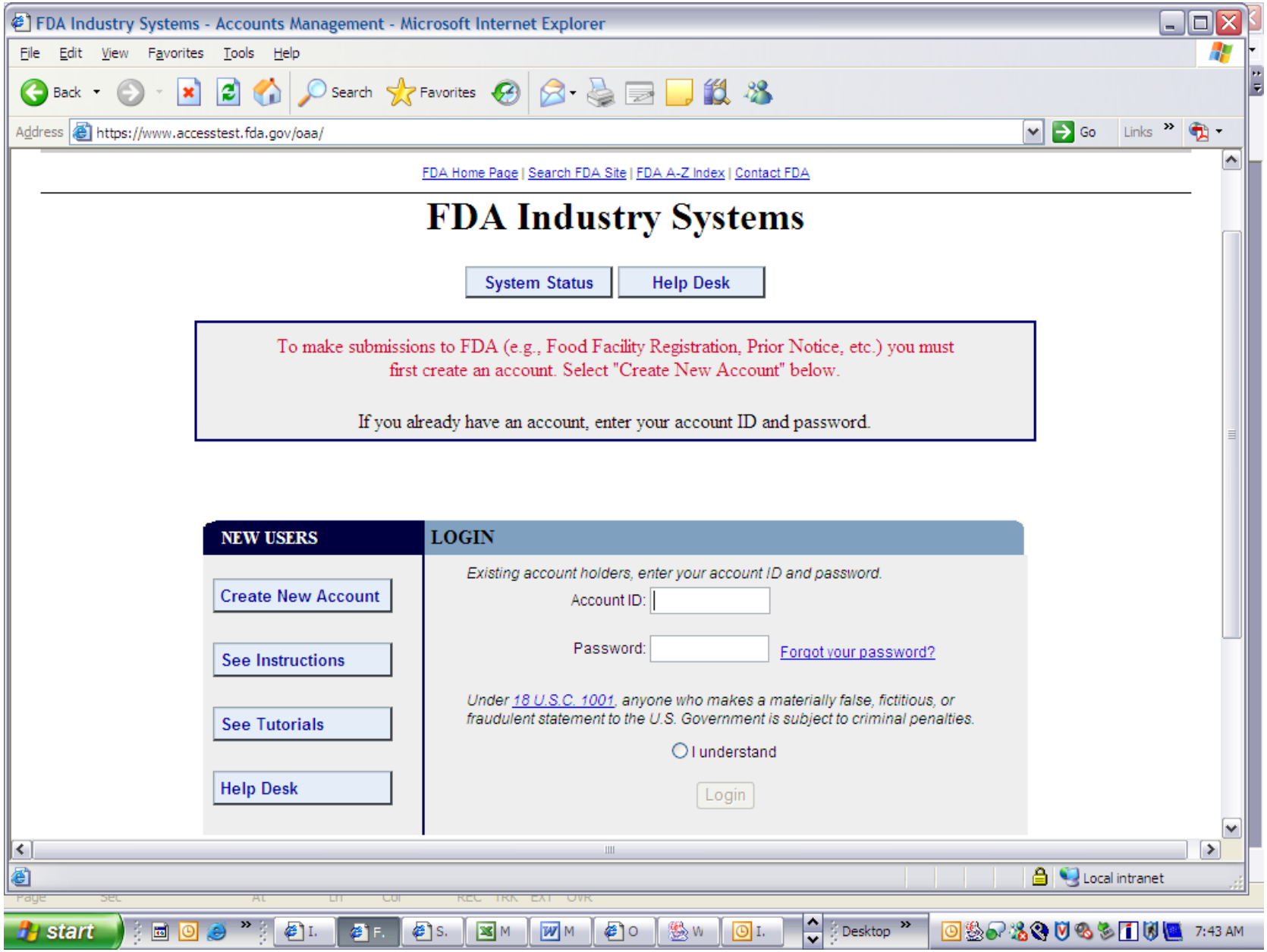
OMB Burden Statement:

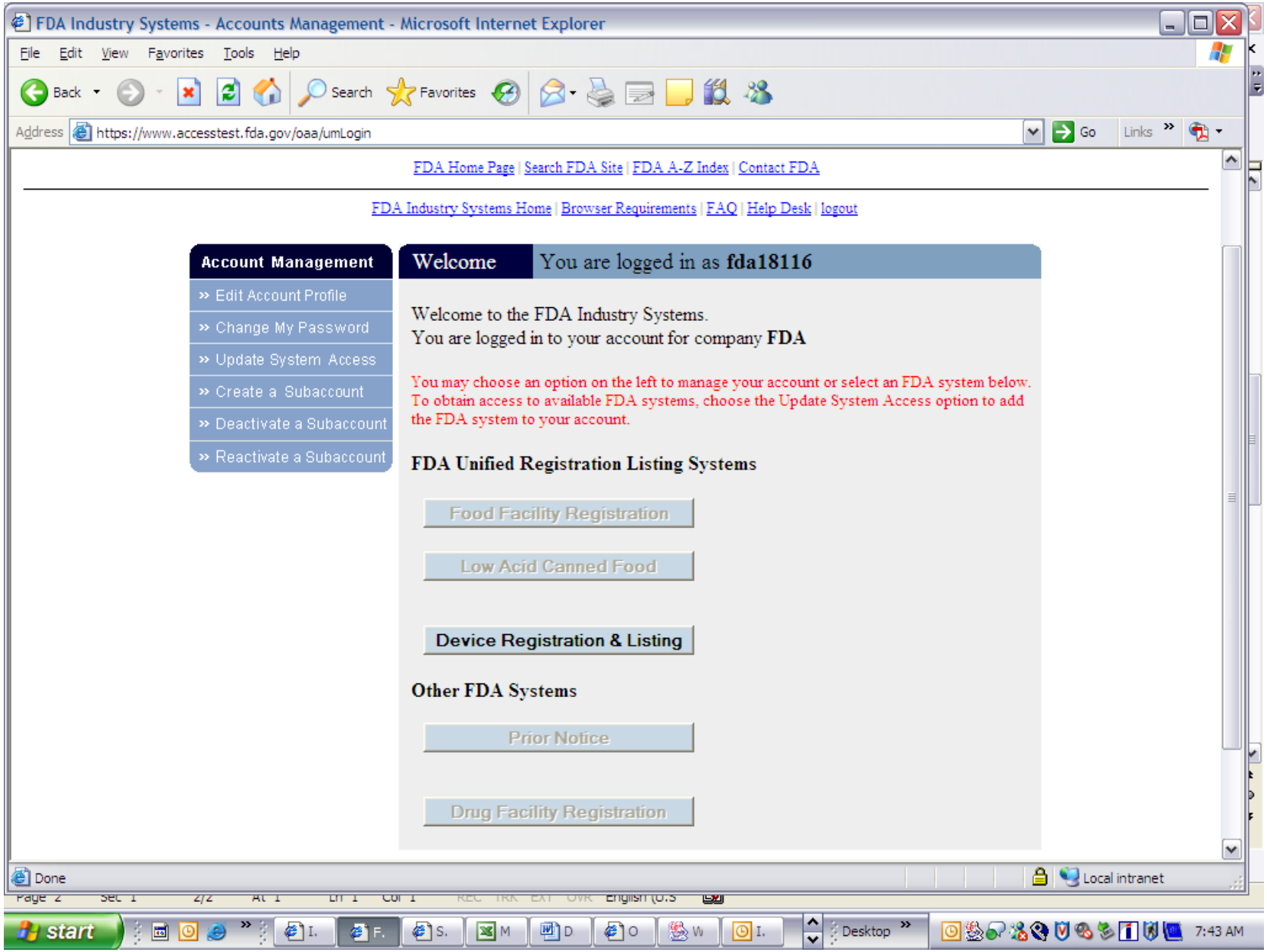
Public reporting burden for this collection of information on Form 3673 is estimated to be 0.50 hours per response for the purpose of firms annually registering their establishment and 0.25 hours per response for the purpose of firms annually listing their devices. These estimates are based on FDA's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

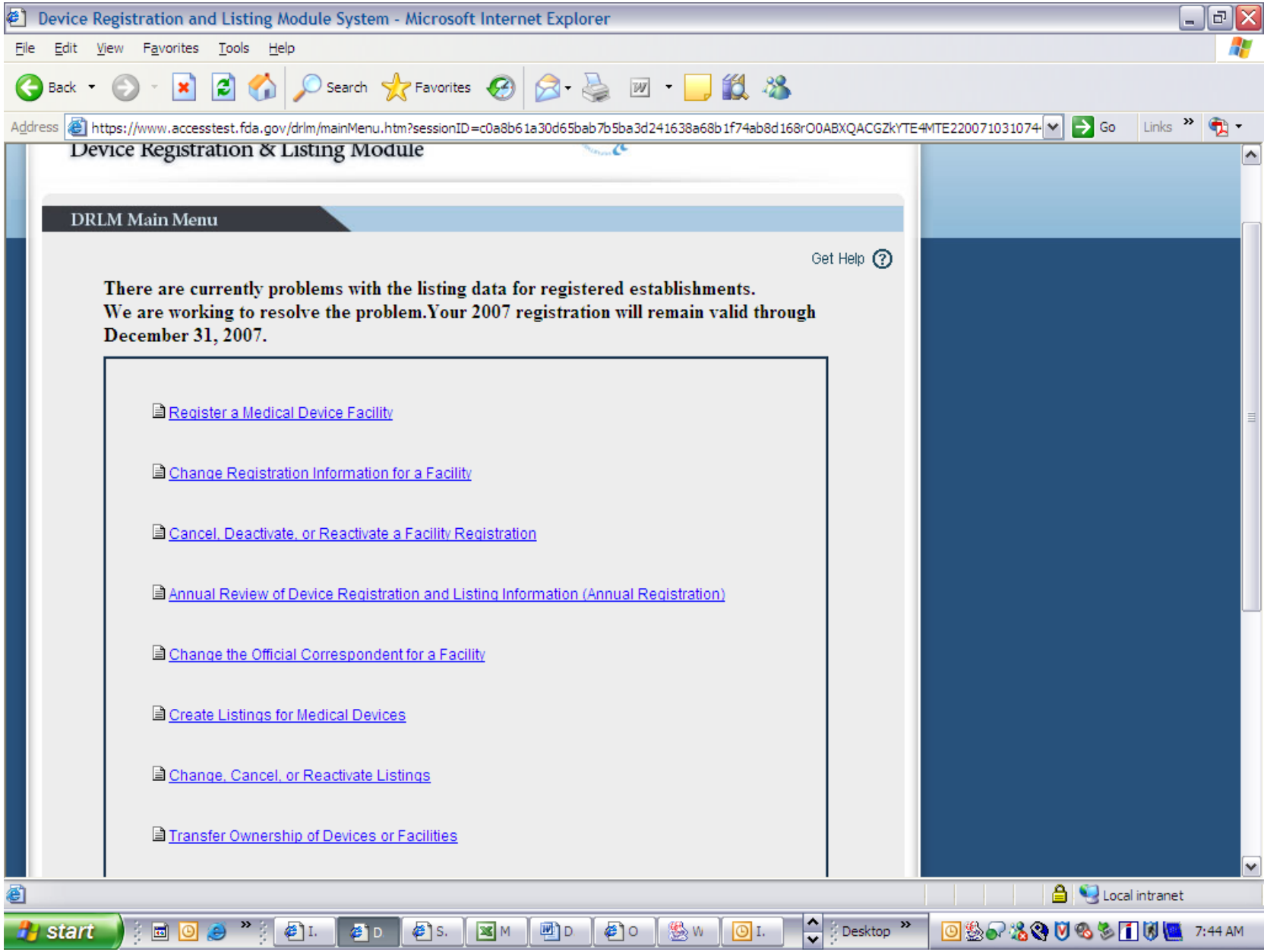
Send comments regarding this burden estimate or another aspect of this collection of information, including suggestions for reducing this burden to:

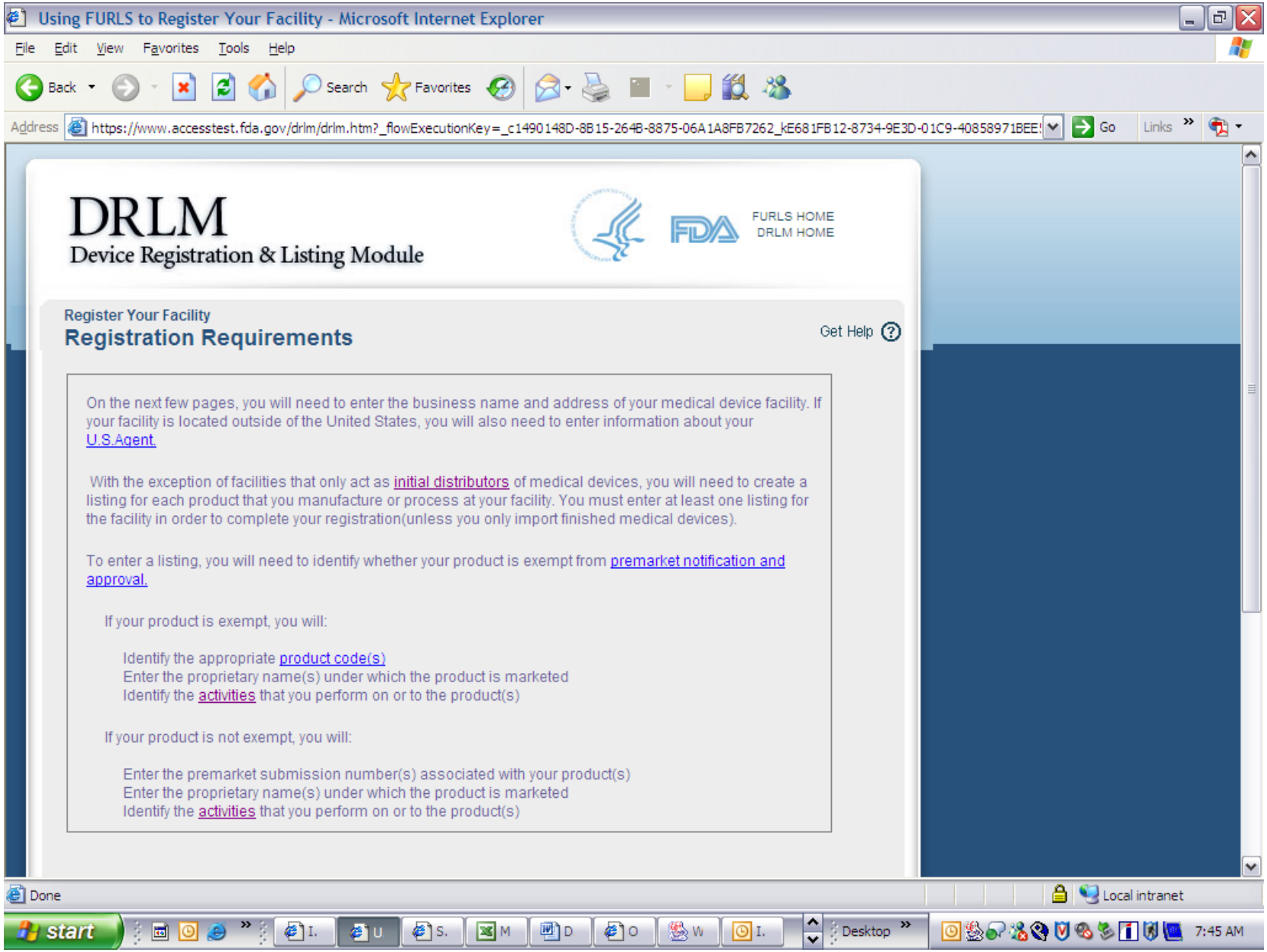
Department of Health and Human Services
Food and Drug Administration
Office of the Chief Information Officer
1350 Piccard Dr.
Rockville, Maryland 20850

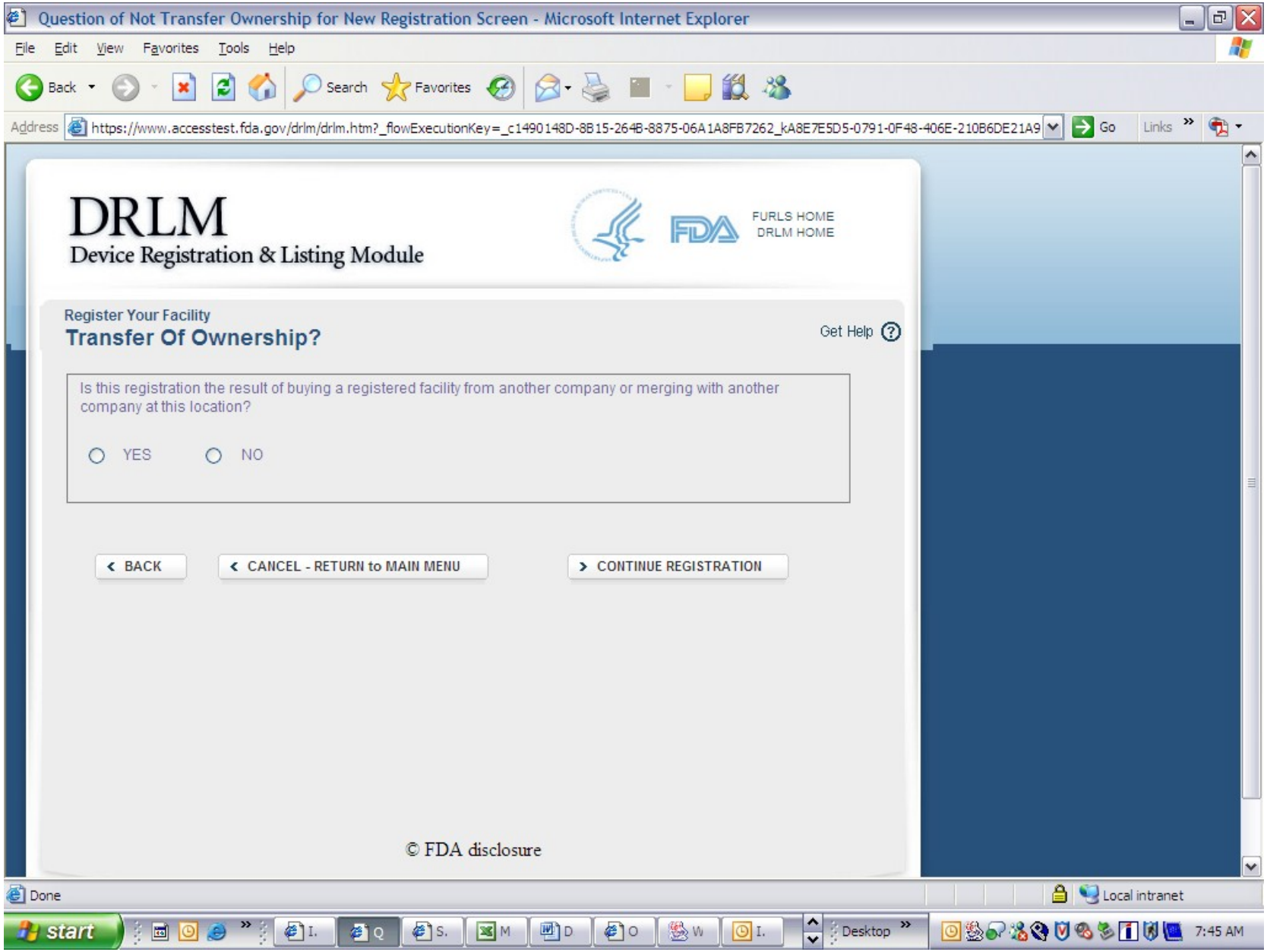
An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number.

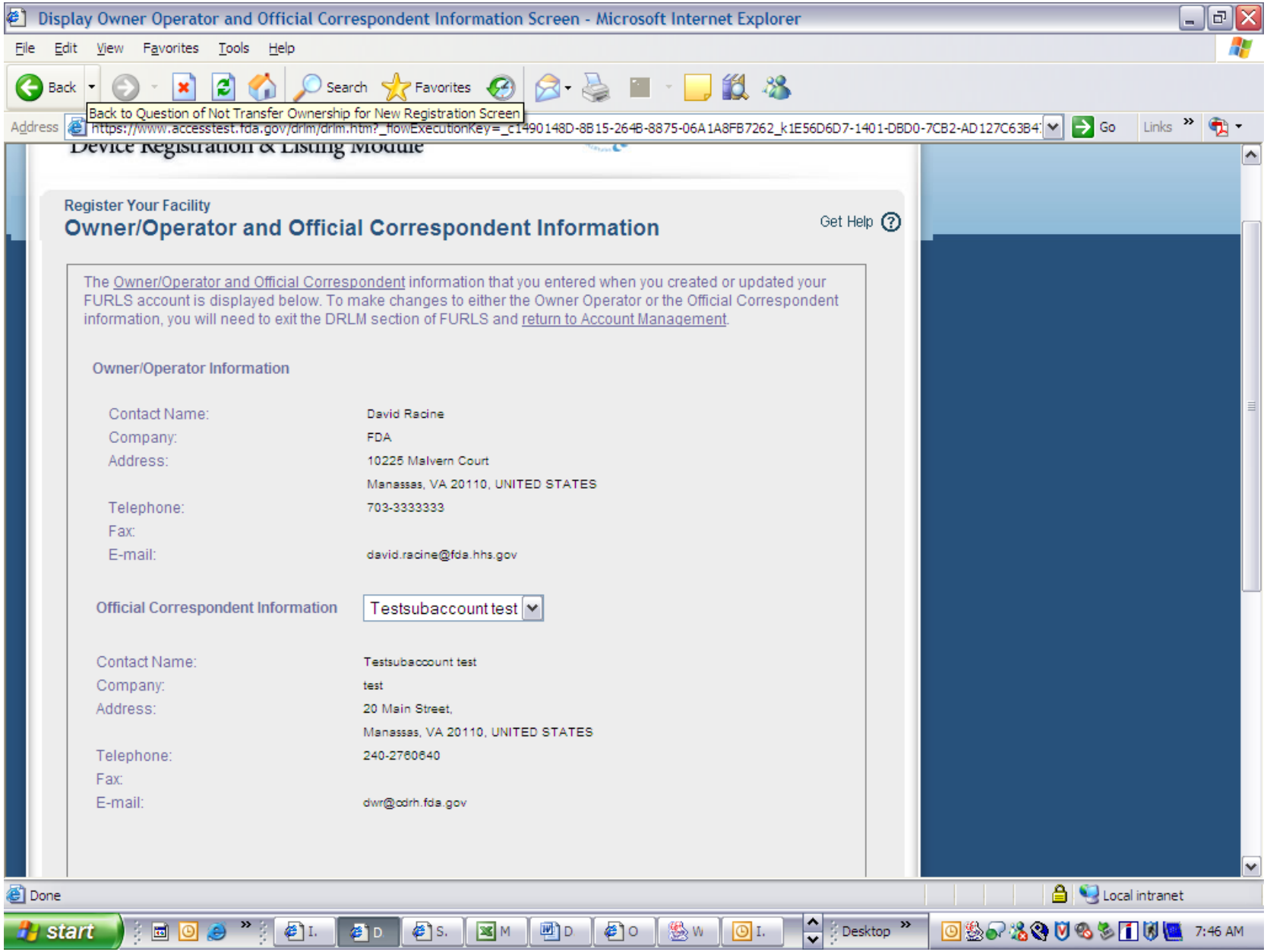

FDA Industry Systems - Accounts Management - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back Search Favorites
Address https://www.accesstest.fda.gov/oaa/
Go Links
FDA Home Page | Search FDA Site | FDA A-Z Index | Contact FDA
FDA Industry Systems
System Status
Help Desk
To make submissions 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.
NEW USERS
LOGIN
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
Local intranet
start
Desktop
7:43 AM

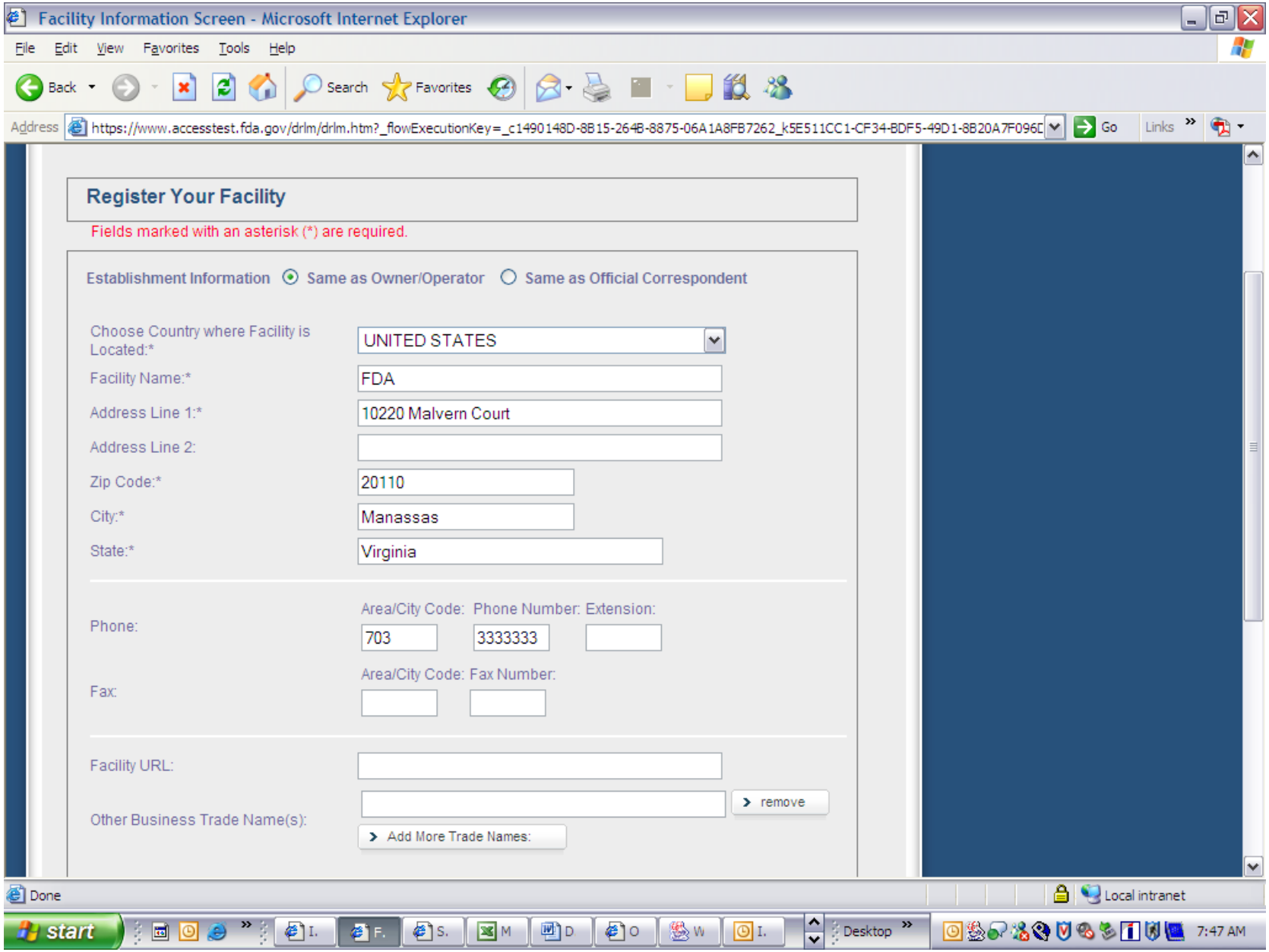

FDA Industry Systems - Accounts Management - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back Search Favorites
Address https://www.accesstest.fda.gov/oaa/umLogin
Go Links
FDA Home Page | Search FDA Site | FDA A-Z Index | Contact FDA
FDA Industry Systems Home | Browser Requirements | 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 fda18116
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
Low Acid Canned Food
Device Registration & Listing
Other FDA Systems
Prior Notice
Drug Facility Registration
Done
Local intranet
start
Desktop
7:43 AM

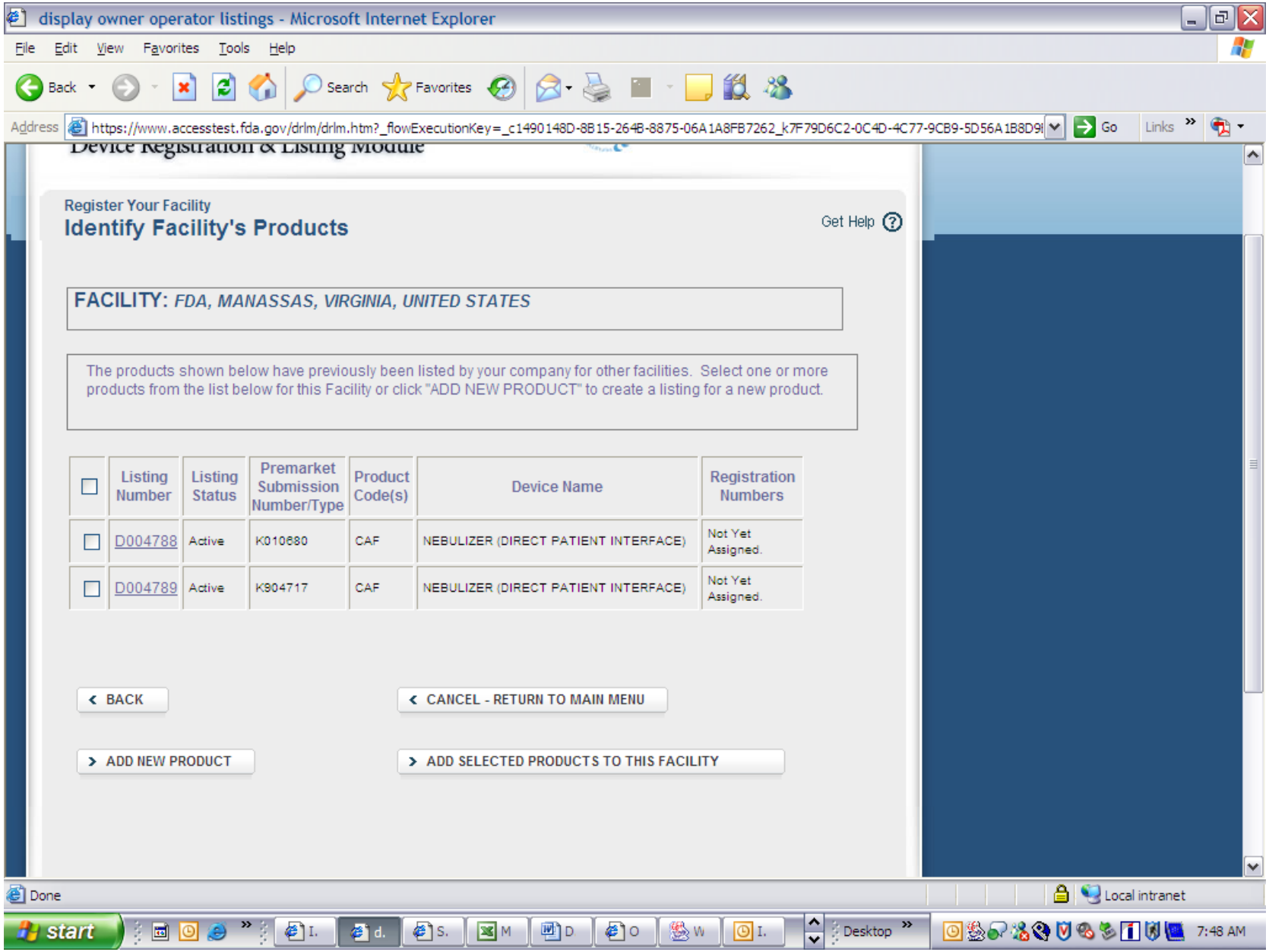

Device Registration and Listing Module System - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back Search Favorites
Address https://www.accesstest.fda.gov/drlm/mainMenu.htm?sessionID=c0a8b61a30d65bab7b5ba3d241638a68b1f74ab8d168rO0ABXQACGZkYTE4MTE220071031074
Go Links
Device Registration & Listing Module
DRLM Main Menu
Get Help
There are currently problems with the listing data for registered establishments.
We are working to resolve the problem.Your 2007 registration will remain valid through December 31, 2007.
Register a Medical Device Facility
Change Registration Information for a Facility
Cancel, Deactivate, or Reactivate a Facility Registration
Annual Review of Device Registration and Listing Information (Annual Registration)
Change the Official Correspondent for a Facility
Create Listings for Medical Devices
Change, Cancel, or Reactivate Listings
Transfer Ownership of Devices or Facilities
Local intranet
start
Desktop
7:44 AM

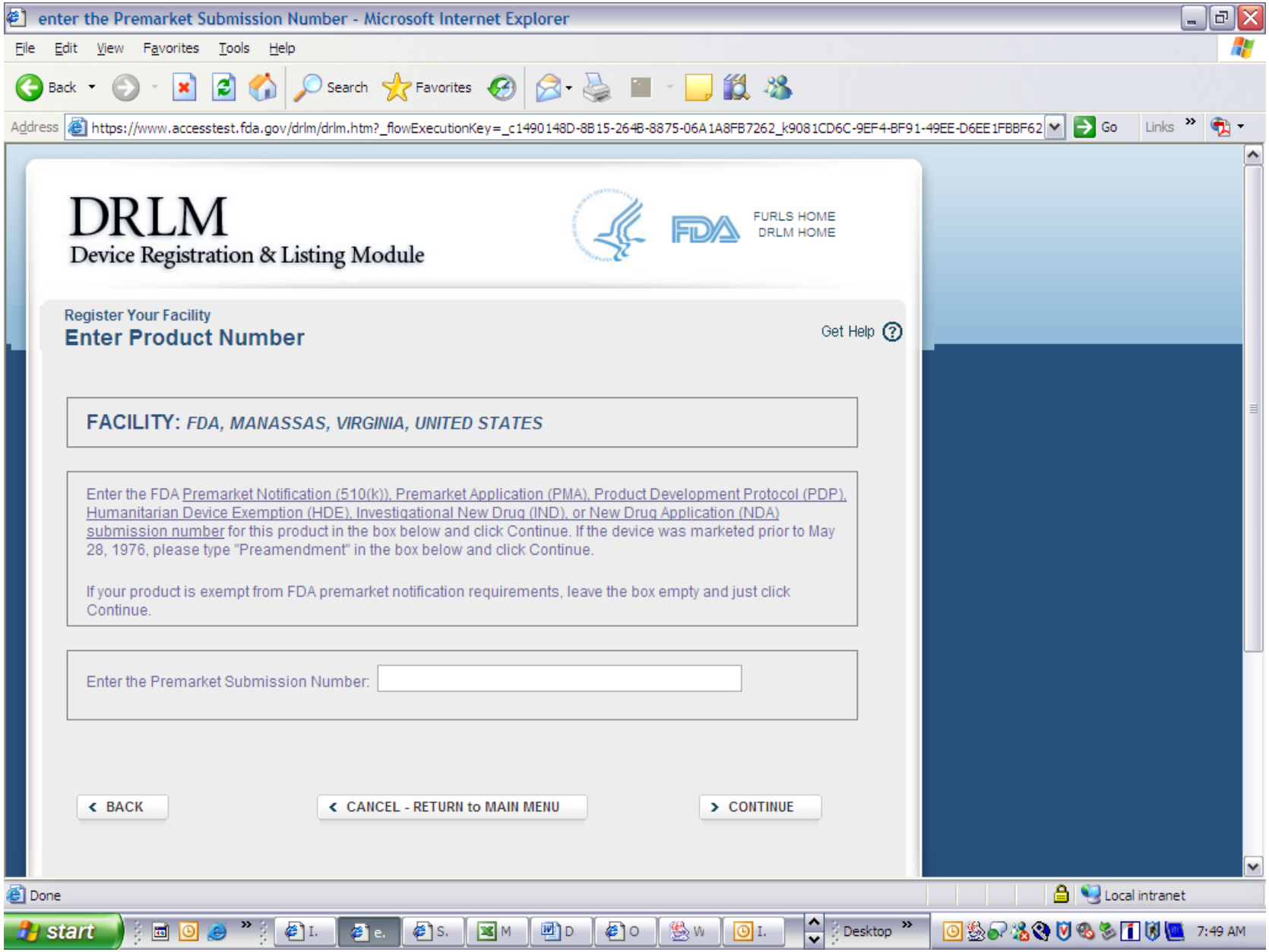

Using FURLS to Register Your Facility - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back Search Favorites
Address https://www.accesstest.fda.gov/drlm/drlm.htm?_flowExecutionKey=_c1490148D-8B15-264B-8875-06A1A8FB7262_kE681FB12-8734-9E3D-01C9-40858971BEE!
Go Links
DRLM
Device Registration & Listing Module
FDA
FURLS HOME
DRLM HOME
Register Your Facility
Registration Requirements
Get Help
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 distributors of medical devices, you will need to create a listing for each product that you manufacture or process at your facility. You must enter at least one listing for the facility in order to complete your registration(unless you only import finished medical devices).
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)
Done
Local intranet
start
Desktop
7:45 AM

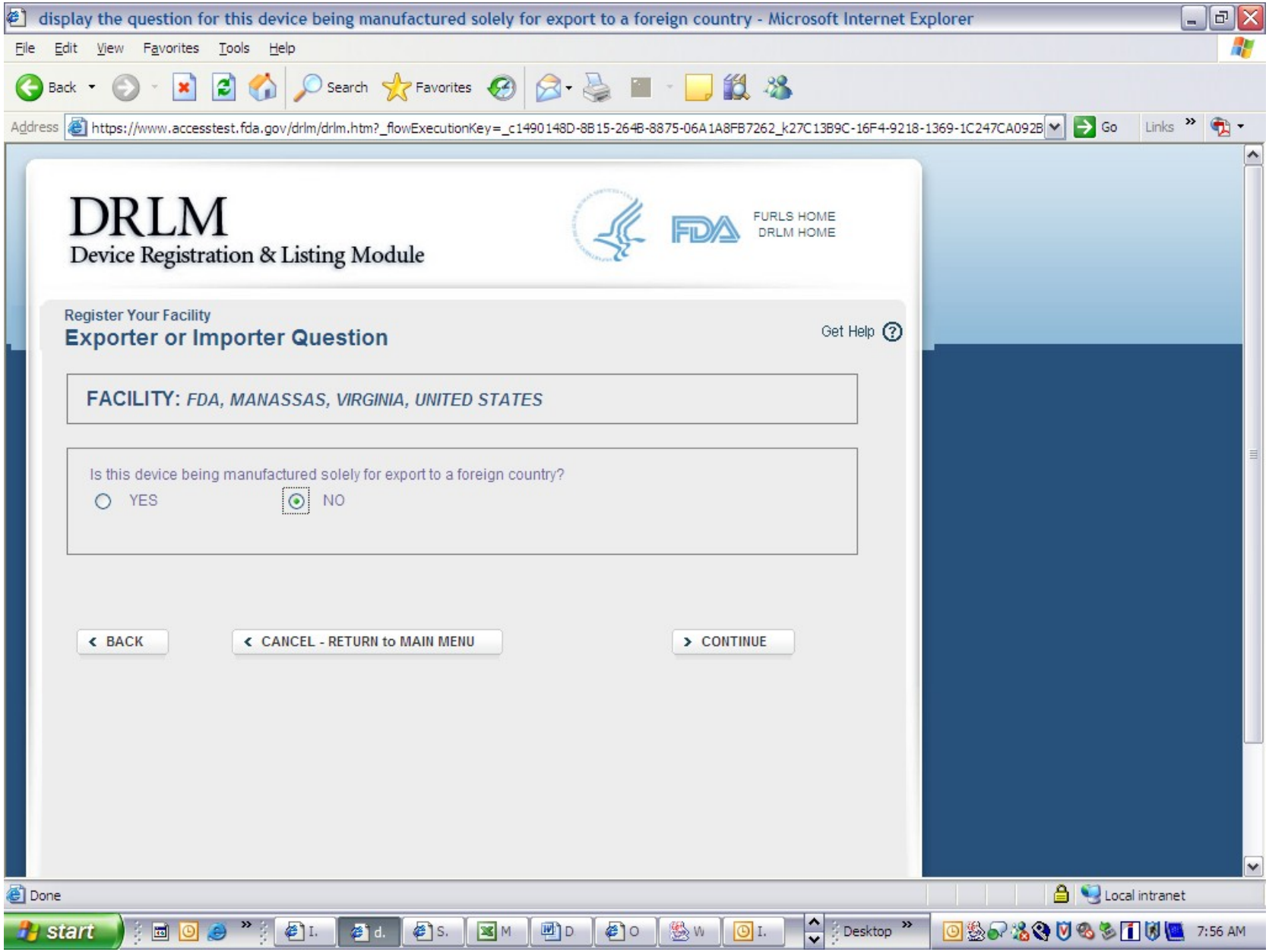

Question of Not Transfer Ownership for New Registration Screen - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back Search Favorites
Address https://www.accesstest.fda.gov/drlm/drlm.htm?_flowExecutionKey=_c1490148D-8B15-264B-8875-06A1A8FB7262_kA8E7E5D5-0791-0F48-406E-210B6DE21A9
Go 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

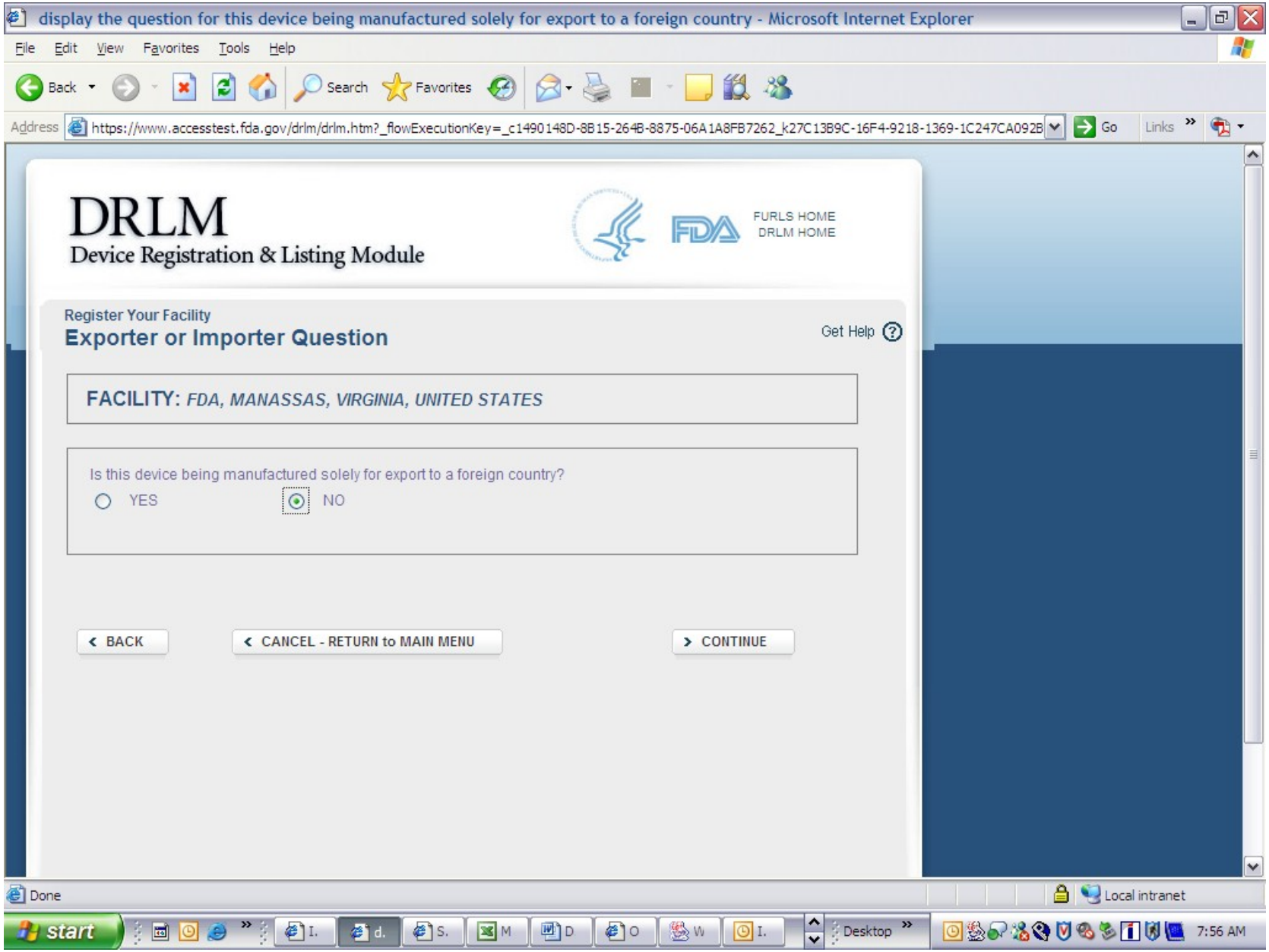

Display Owner Operator and Official Correspondent Information Screen - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back
Search
Favorites
Back to Question of Not Transfer Ownership for New Registration Screen
Address
https://www.accesstest.fda.gov/drlm/drlm.htm?_flowExecutionKey=_c1490148D-8B15-264B-8875-06A1A8FB7262_k1E56D6D7-1401-DBD0-7CB2-A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

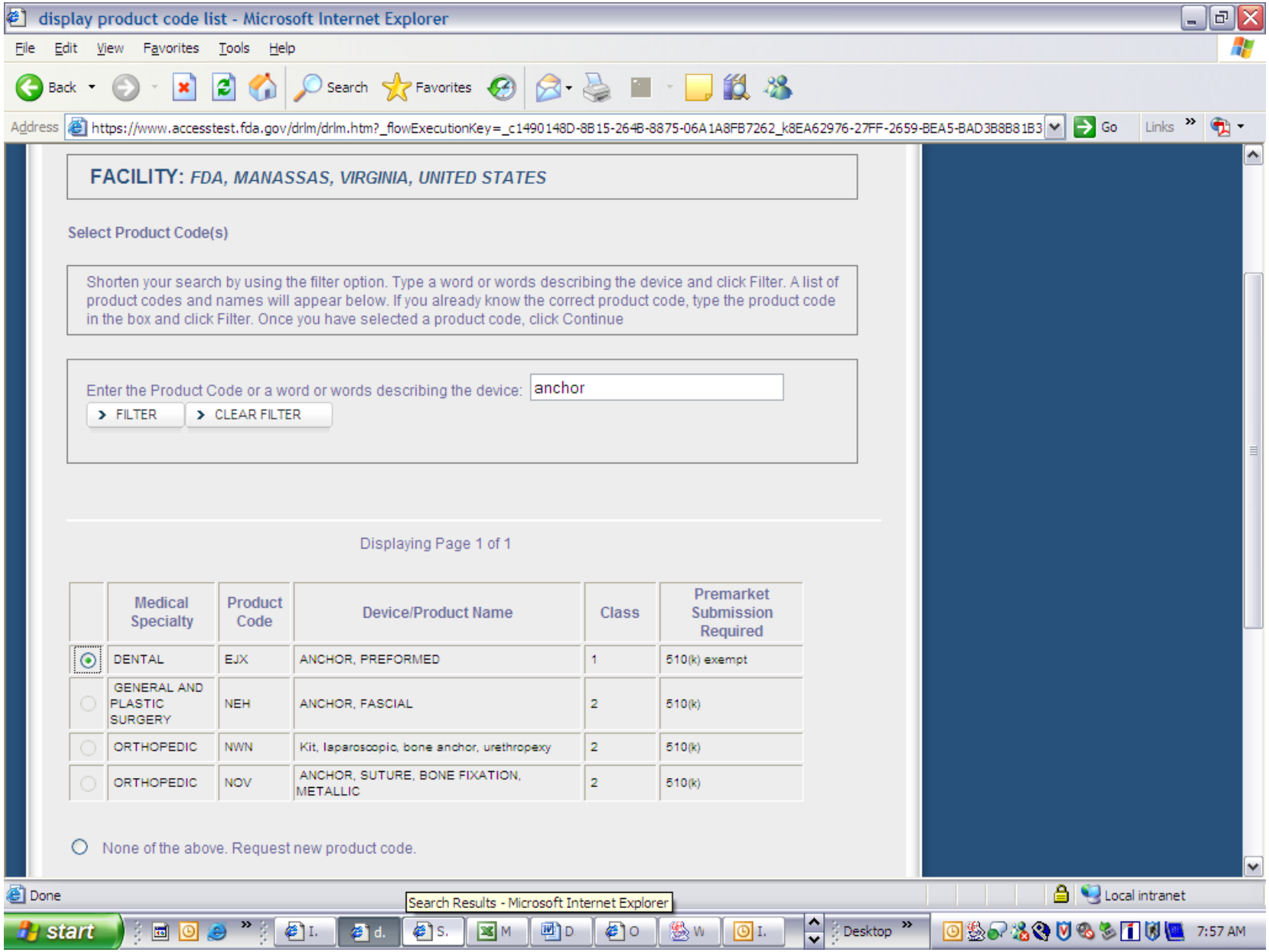

Facility Information Screen - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back Search Favorites
Address https://www.accesstest.fda.gov/drlm/drlm.htm?_flowExecutionKey=_c1490148D-8B15-264B-8875-06A1A8FB7262_k5E511CC1-CF34-BDF5-49D1-8B20A7F096D
Go Links
Register Your Facility
Fields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

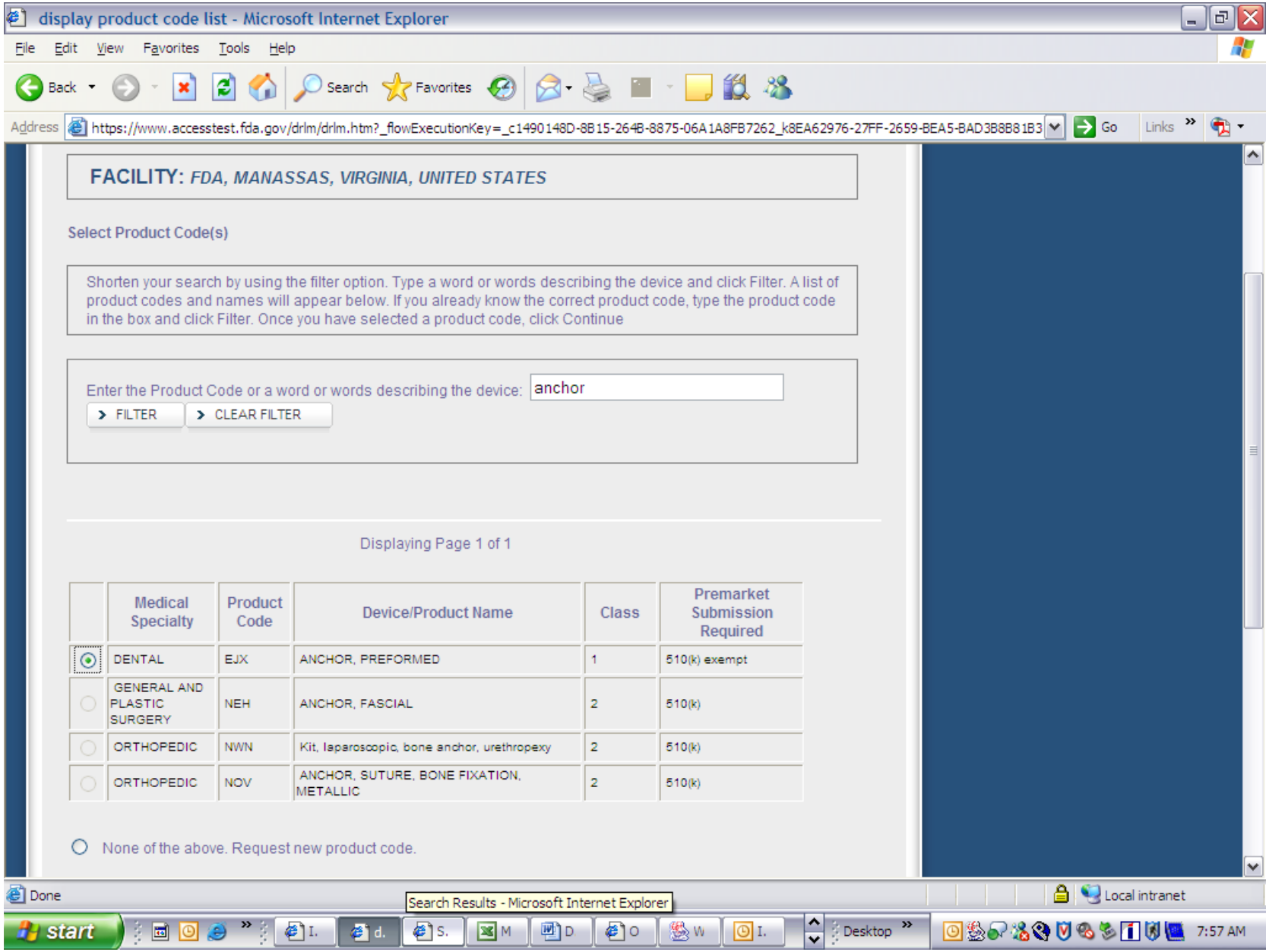

display owner operator listings - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back Search Favorites
Address https://www.accesstest.fda.gov/drlm/drlm.htm?_flowExecutionKey=_c1490148D-8B15-264B-8875-06A1A8FB7262_k7F79D6C2-0C4D-4C77-9CB9-5D56A1B8D9
Go Links
Device Registration & Listing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

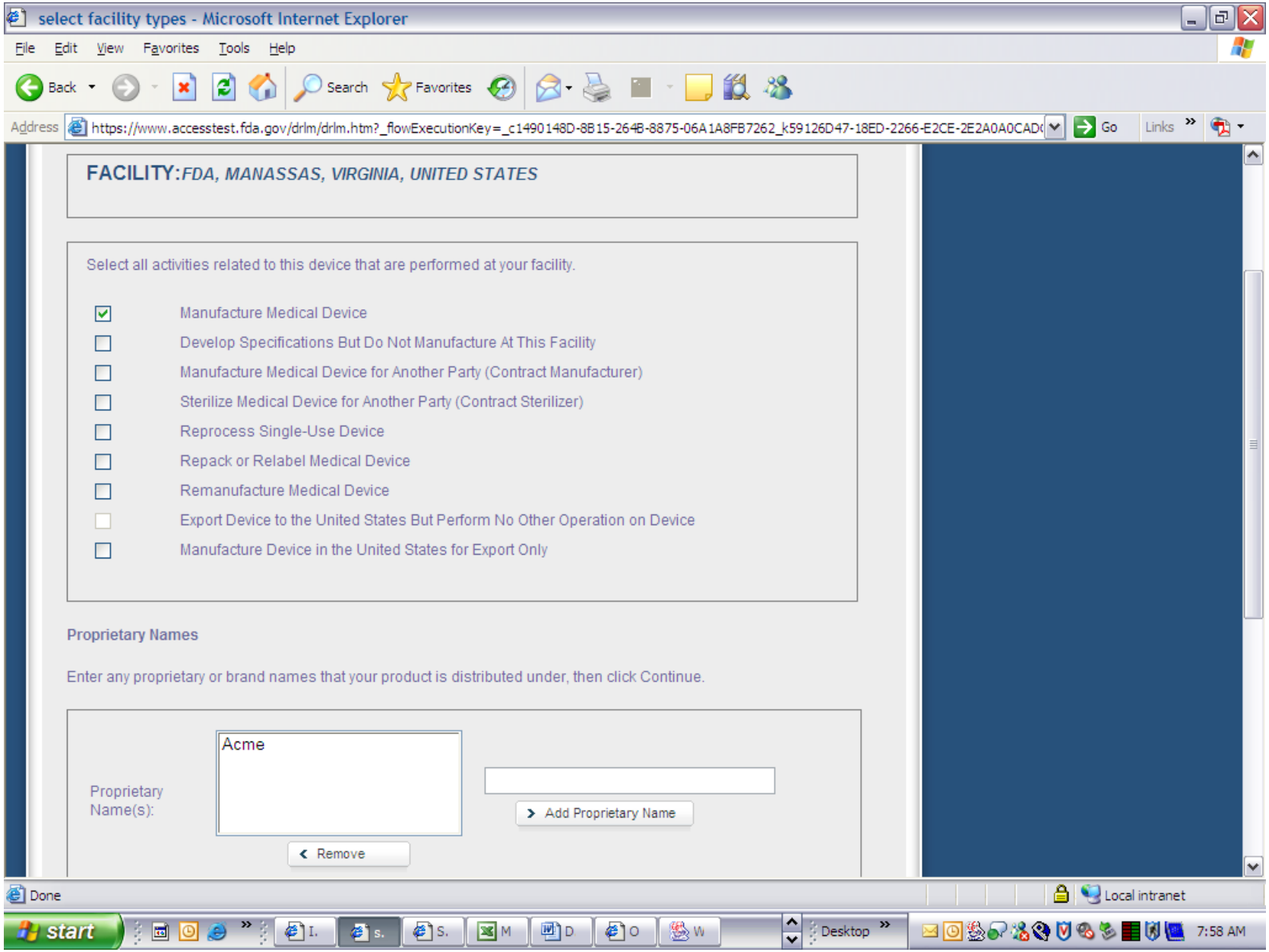

enter the Premarket Submission Number - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back Search Favorites
Address https://www.accesstest.fda.gov/drlm/drlm.htm?_flowExecutionKey=_c1490148D-8B15-264B-8875-06A1A8FB7262_k9081CD6C-9EF4-BF91-49EE-D6EE1FBBF62
Go Links
DRLM
Device Registration & Listing Module
FDA
FURLS HOME
DRLM HOME
Register Your Facility
Enter Product Number
Get Help
FACILITY: FDA, MANASSAS, VIRGINIA, UNITED STATES
Enter the FDA Premarket Notification (510(k)), Premarket Application (PMA), Product Development Protocol (PDP), Humanitarian Device Exemption (HDE), Investigational New Drug (IND), or New Drug Application (NDA) submission number for this product in the box below and click Continue. If the device was marketed prior to May 28, 1976, please type "Preamendment" in the box below and click Continue.
If your product is exempt from FDA premarket notification requirements, leave the box empty and just click Continue.
Enter the Premarket Submission Number:
BACK
CANCEL - RETURN to MAIN MENU
CONTINUE
Done
Local intranet
start
Desktop
7:49 AM

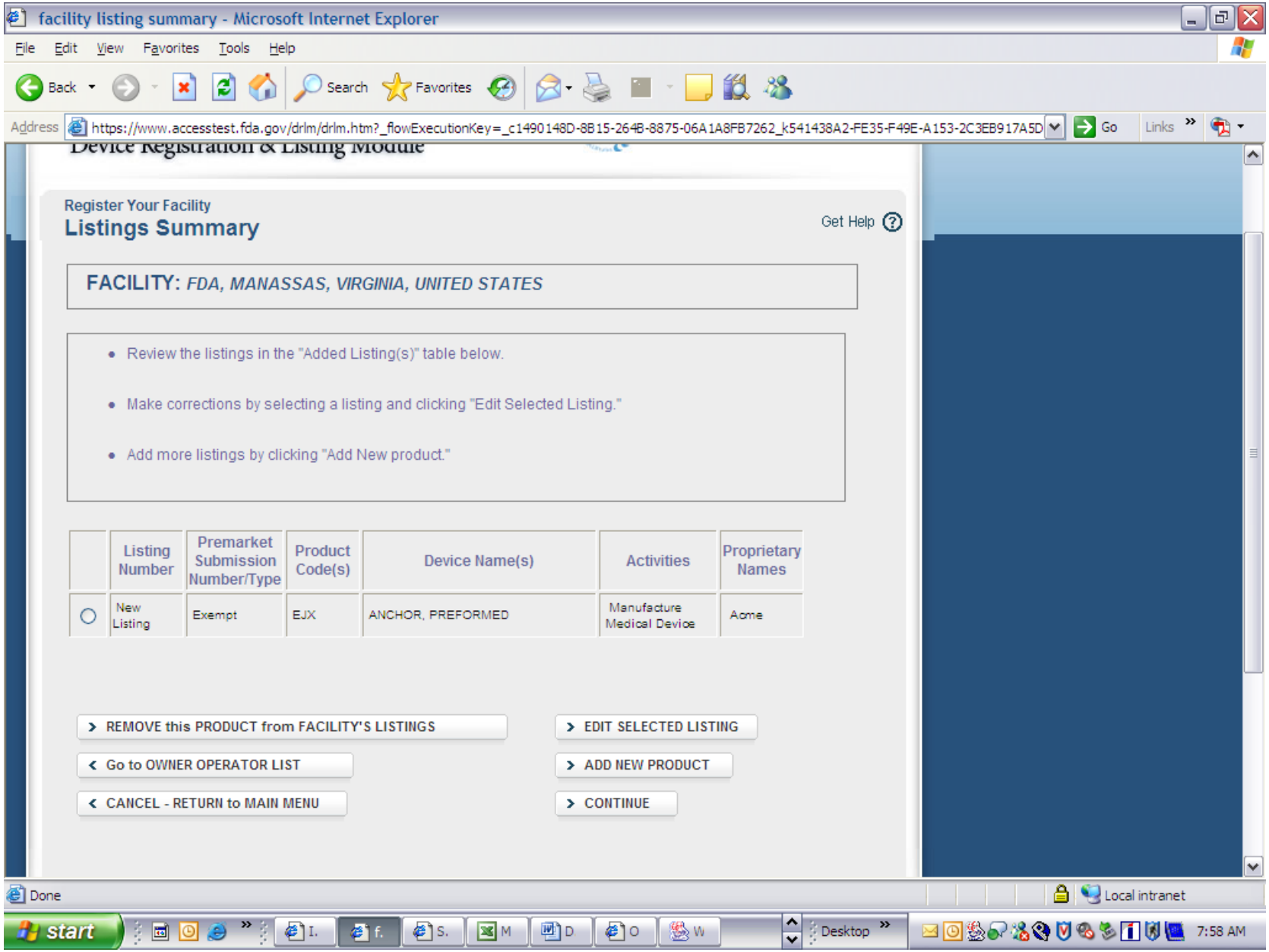

display the question for this device being manufactured solely for export to a foreign country - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back Search Favorites
Address https://www.accesstest.fda.gov/drlm/drlm.htm?_flowExecutionKey=_c1490148D-8B15-264B-8875-06A1A8FB7262_k27C13B9C-16F4-9218-1369-1C247CA092B
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

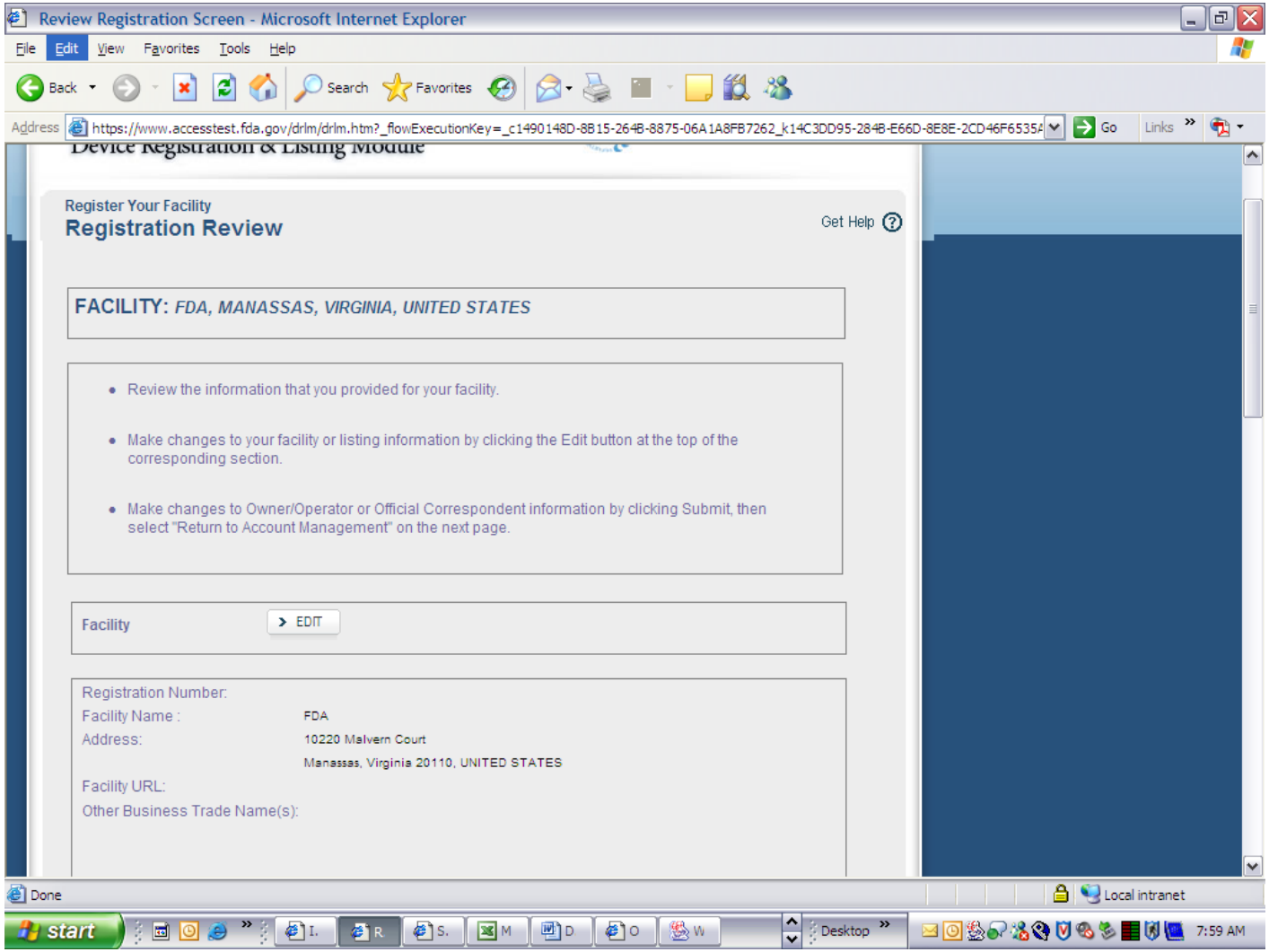

display the question for this device being manufactured solely for export to a foreign country - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back Search Favorites
Address https://www.accesstest.fda.gov/drlm/drlm.htm?_flowExecutionKey=_c1490148D-8B15-264B-8875-06A1A8FB7262_k27C13B9C-16F4-9218-1369-1C247CA092B
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

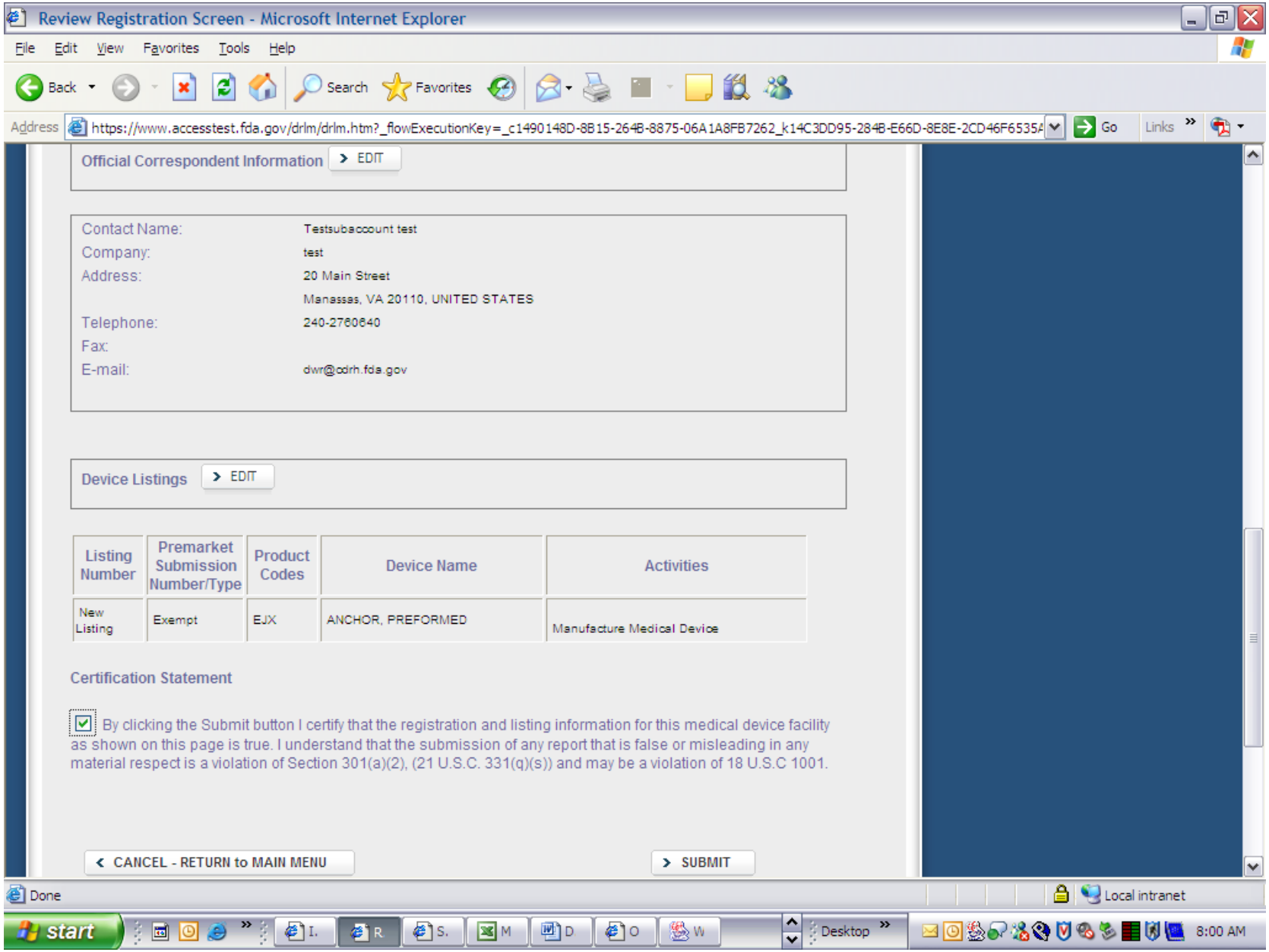

display product code list - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back Search Favorites
Address https://www.accesstest.fda.gov/drlm/drlm.htm?_flowExecutionKey=_c1490148D-8B15-264B-8875-06A1A8FB7262_k8EA62976-27FF-2659-BEA5-BAD3B8B81B3
Go Links
FACILITY: FDA, MANASSAS, VIRGINIA,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

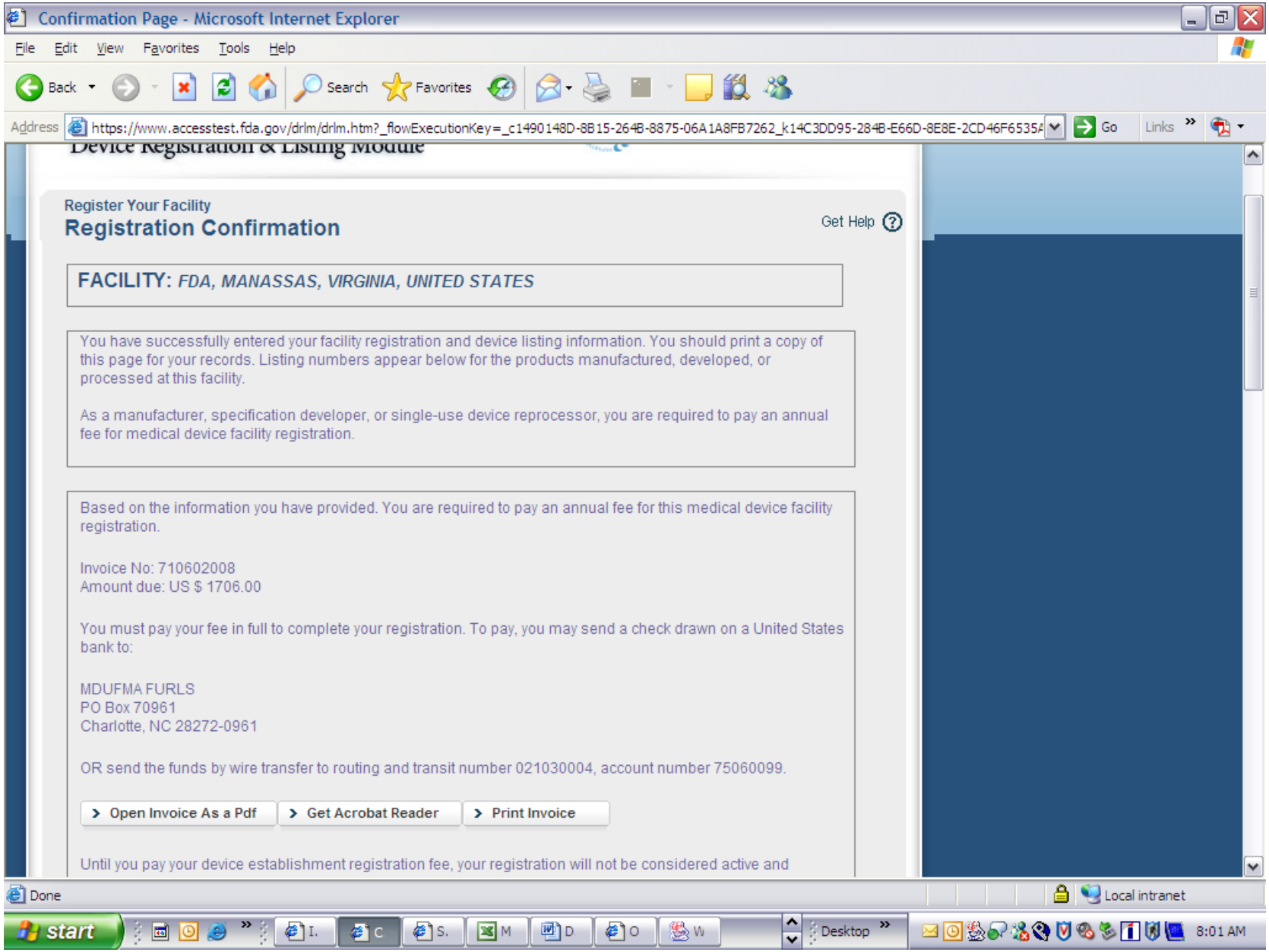

display product code list - Microsoft Internet Explorer
File Edit View Favorites Tools Help
Back Search Favorites
Address https://www.accesstest.fda.gov/drlm/drlm.htm?_flowExecutionKey=_c1490148D-8B15-264B-8875-06A1A8FB7262_k8EA62976-27FF-2659-BEA5-BAD3B8B81B3
Go Links
FACILITY: FDA, MANASSAS, VIRGINIA, 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 - 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_k59126D47-18ED-2266-E2CE-2E2A0A0CAD
Go Links
FACILITY: FDA, MANASSAS, VIRGINIA, 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 Medical Device for Another Party (Contract Manufacturer)
Sterilize 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
Proprietary Names
Enter any proprietary or brand names that your product is distributed under, then click Continue.
Proprietary Name(s):
Acme
Add Proprietary Name
Remove
Done
Local intranet
start
Desktop
7:58 AM


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 - 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_k14C3DD95-284B-E66D-8E8E-2CD46F6535A
Go Links
Device Registration & Listing Module
Register Your Facility
Registration Review
Get Help
FACILITY: FDA, MANASSAS, VIRGINIA, UNITED STATES
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 select "Return to Account Management" on the next page.
Facility
EDIT
Registration Number:
Facility Name : FDA
Address: 10220 Malvern Court
Manassas, Virginia 20110, UNITED STATES
Facility URL:
Other Business Trade Name(s):
Done
Local intranet
start
Desktop
7:59 AM


Review 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_k14C3DD95-284B-E66D-8E8E-2CD46F6535A
Go Links
Official Correspondent Information
EDIT
Contact Name: Testsubaccount test
Company: test
Address: 20 Main Street
Manassas, VA 20110, UNITED STATES
Telephone: 240-2760640
Fax:
E-mail: dwr@cdrh.fda.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(a)(2), (21 U.S.C. 331(q)(s)) and may be a violation of 18 U.S.C 1001.
CANCEL - RETURN to MAIN MENU
SUBMIT
Done
Local intranet
start
Desktop
8:00 AM


Confirmation Page - Microsoft Internet Explorer
File Edit View Favorites Tools Help
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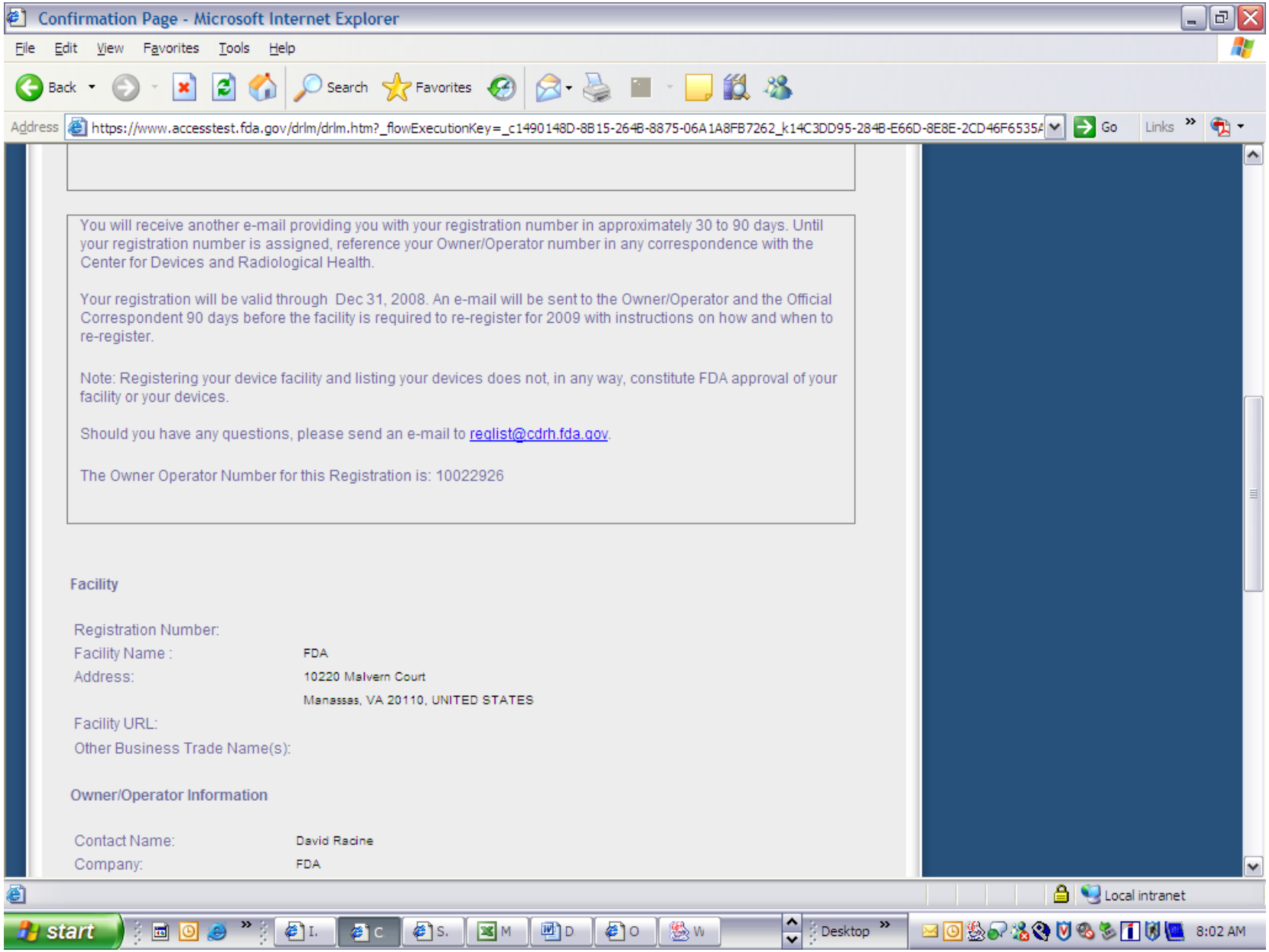
Address https://www.accesstest.fda.gov/drlm/drlm.htm?_flowExecutionKey=_c1490148D-8B15-264B-8875-06A1A8FB7262_k14C3DD95-284B-E66D-8E8E-2CD46F6535A
Go Links
Device Registration & Listing Module
Register Your Facility
Registration Confirmation
Get Help
FACILITY: FDA, MANASSAS, VIRGINIA, UNITED STATES
You have successfully entered your facility registration and device listing information. You should print a copy of this page for your records. Listing numbers appear below for the products manufactured, developed, or processed at this facility.
As a manufacturer, specification developer, or single-use device reprocessor, you are required to pay an annual fee for medical device facility registration.
Based on the information you have provided. You are required to pay an annual fee for this medical device facility registration.
Invoice No: 710602008
Amount due: US $ 1706.00
You must pay your fee in full to complete your registration. To pay, you may send a check drawn on a United States bank to:
MDUFMA FURLS
PO Box 70961
Charlotte, NC 28272-0961
OR send the funds by wire transfer to routing and transit number 021030004, account number 75060099.
Open Invoice As a Pdf
Get Acrobat Reader
Print Invoice
Until you pay your device establishment registration fee, your registration will not be considered active and
Done
Local intranet
start
Desktop
8:01 AM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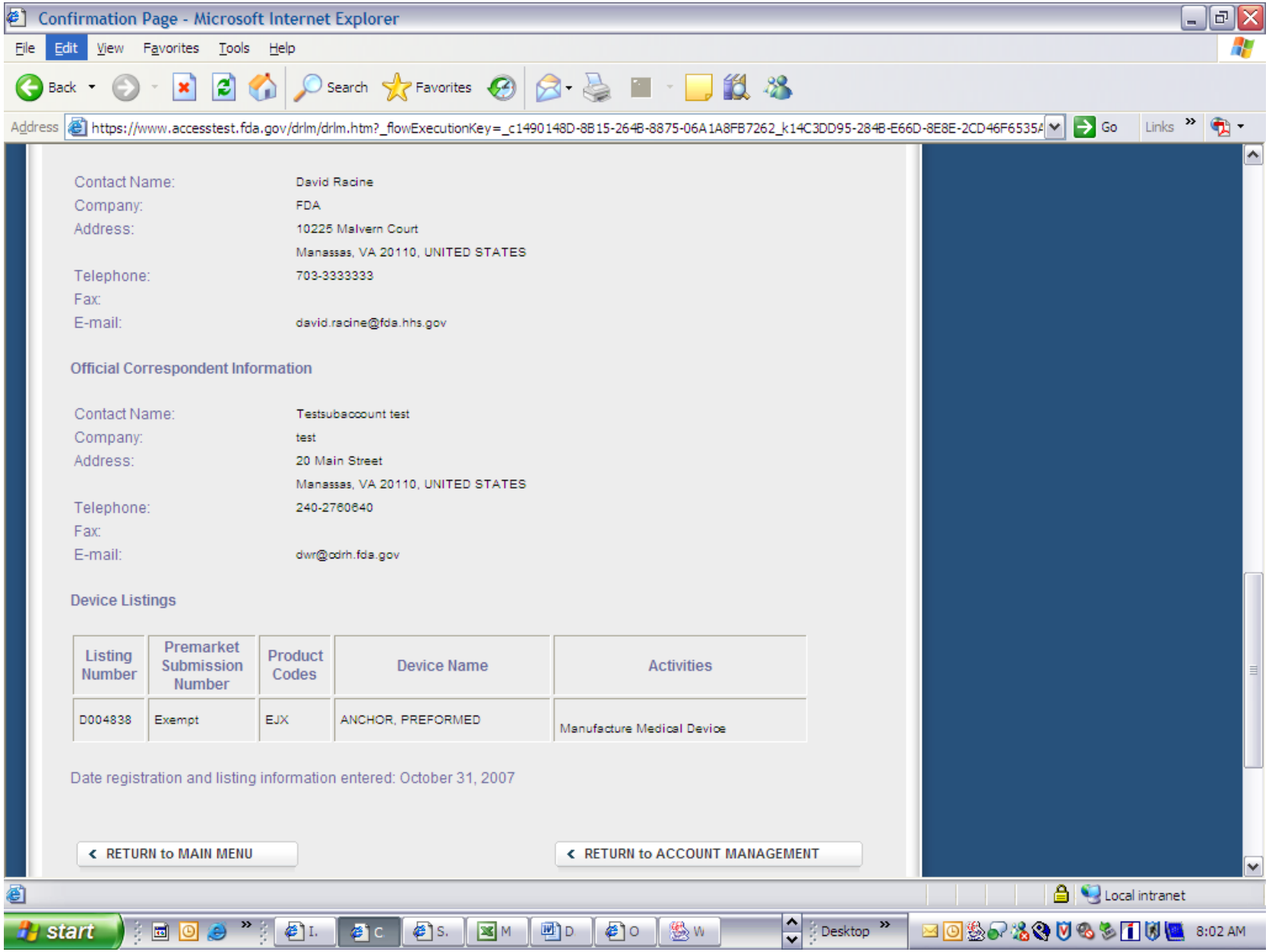
Address https://www.accesstest.fda.gov/drlm/drlm.htm?_flowExecutionKey=_c1490148D-8B15-264B-8875-06A1A8FB7262_k14C3DD95-284B-E66D-8E8E-2CD46F6535A
Go Links
You will receive another e-mail providing you with your registration number in approximately 30 to 90 days. Until your registration number is assigned, reference your Owner/Operator number in any correspondence with the Center for Devices and Radiological Health.
Your registration will be valid through Dec 31, 2008. An e-mail will be sent to the Owner/Operator and the Official Correspondent 90 days before the facility is required to re-register for 2009 with instructions on how and when to re-register.
Note: Registering your device facility and listing your devices does not, in any way, constitute FDA approval of your facility or your devices.
Should you have any questions, please send an e-mail to reglist@cdrh.fda.gov.
The Owner Operator Number for this Registration is: 10022926
Facility
Registration Number:
Facility Name : FDA
Address: 10220 Malvern Court
Manassas, VA 20110, UNITED STATES
Facility URL:
Other Business Trade Name(s):
Owner/Operator Information
Contact Name: David Racine
Company: FDA
Local intranet
start
Desktop
8:02 AM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Go Links
Contact Name: David Racine
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Fax:
E-mail: david.racine@fda.hhs.gov
Official Correspondent Information
Contact Name: Testsubaccount test
Company: test
Address: 20 Main Street
Manassas, VA 20110, UNITED STATES
Telephone: 240-2760640
Fax:
E-mail: dwr@cdrh.fda.gov
Device Listings
Listing Number
Premarket Submission Number
Product Codes
Device Name
Activities
D004838
Exempt
EJX
ANCHOR, PREFORMED
Manufacture Medical Device
Date registration and listing information entered: October 31, 2007
RETURN to MAIN MENU
RETURN to ACCOUNT MANAGEMENT
Local intranet
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Desktop
8:02 AM