

Device Registration and Listing Module

Form Number: FDA 3673(03/08)

OMB Number: 0910-3673

OMB Expiration Date: 01//31/2009

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:

Department of Health and Human Services
Food and Drug Administration
Office of the Chief Information Officer (HFA-250)
5600 Fishers Lane
Rockville, Maryland 20857

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

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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

[Create New Account](#)

[See Instructions](#)

[See Tutorials](#)

[Help Desk](#)

LOGIN

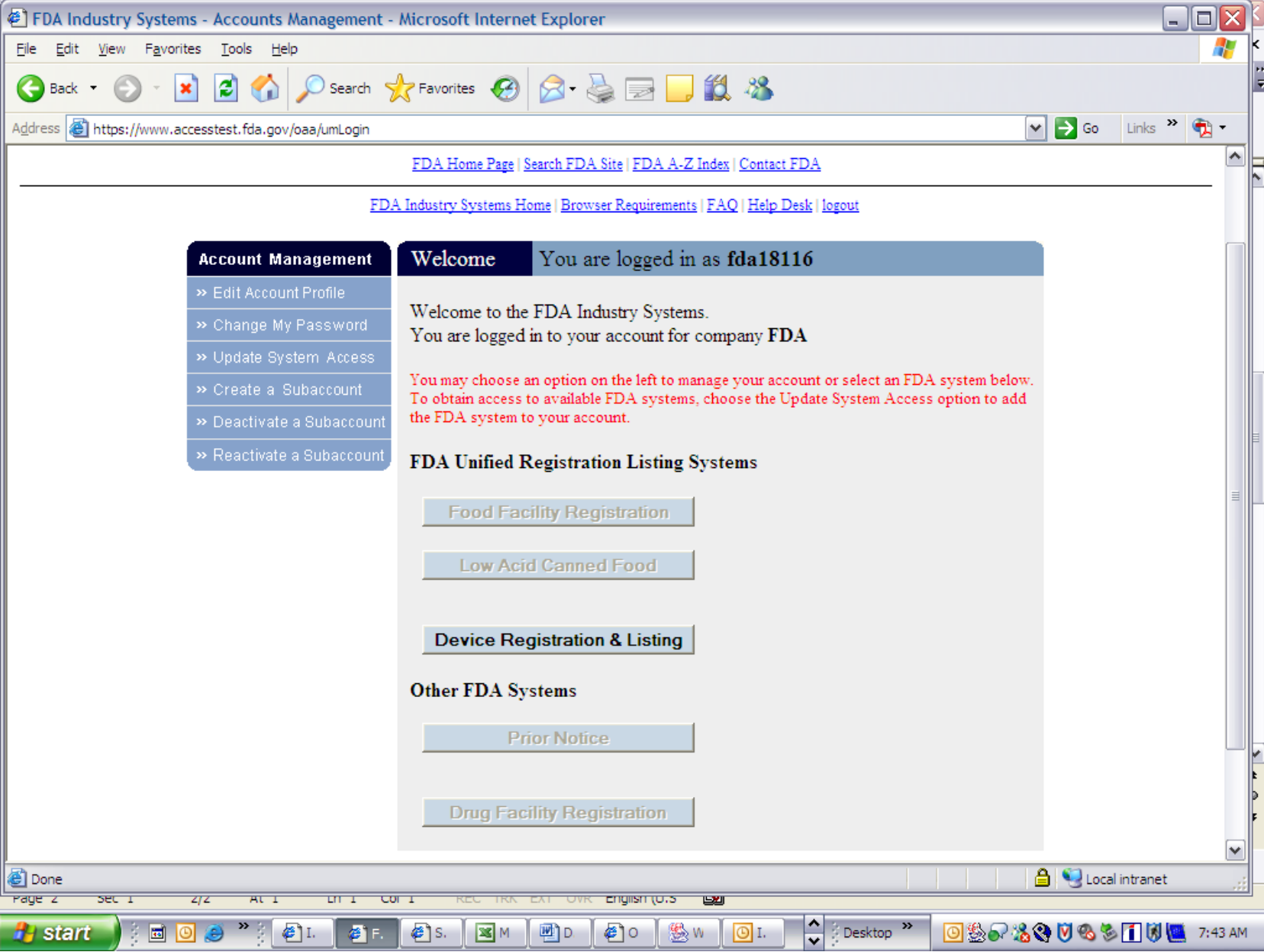
Existing account holders, enter your account ID and password.

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



The screenshot displays a Microsoft Internet Explorer browser window. The address bar shows the URL: <https://www.access.gpo.gov/drlm/mainMenu.htm?sessionID=c0a8b61a30d65bab7b5ba3d241638a68b1f74ab8d168r00ABXQACGZkYTE4MTE220071031074>. The page title is "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](#)

The Windows taskbar at the bottom shows the Start button, several open application windows (I., D., S., M., D., O., W., I.), and the system tray with the time 7:44 AM and "Local intranet" indicator.

DRLM

Device Registration & Listing Module



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)

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](#)

© FDA disclosure

Display Owner Operator and Official Correspondent Information Screen - Microsoft Internet Explorer

File Edit View Favorites Tools Help

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Address https://www.access.gpo.gov/drlm/drlm.htm?_flowExecutionKey=_c1490148D-8B15-264B-8875-06A1A8FB7262_k1E56D6D7-1401-DBD0-7CB2-AD127C6384 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

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Address https://www.access.gpo.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: Phone Number: Extension:
703 3333333

Fax: Area/City Code: Fax Number:

Facility URL:

Other Business Trade Name(s):

Done Local intranet

start Desktop 7:47 AM

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	K010680	CAF	NEBULIZER (DIRECT PATIENT INTERFACE)	Not Yet Assigned.
<input type="checkbox"/>	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

enter the Premarket Submission Number - Microsoft Internet Explorer


File Edit View Favorites Tools Help

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Address https://www.accessgtd.fda.gov/drlm/drlm.htm?_flowExecutionKey=_c1490148D-8B15-264B-8875-06A1A8FB7262_k9081CD6C-9EF4-8F91-49EE-D6EE1FBFF62 Go Links

DRLM

Device Registration & Listing Module



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

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

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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 - Microsoft Internet Explorer

File Edit View Favorites Tools Help

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Address https://www.accessgtd.fda.gov/drlm/drlm.htm?_flowExecutionKey=_c1490148D-8B15-264B-8875-06A1A8FB7262_k59126D47-18ED-2266-E2CE-2E2A0A0CAD0 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):

Done Local intranet

start Desktop 7:58 AM

facility listing summary - Microsoft Internet Explorer

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Address https://www.accessdata.fda.gov/drldm/drldm.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 ?

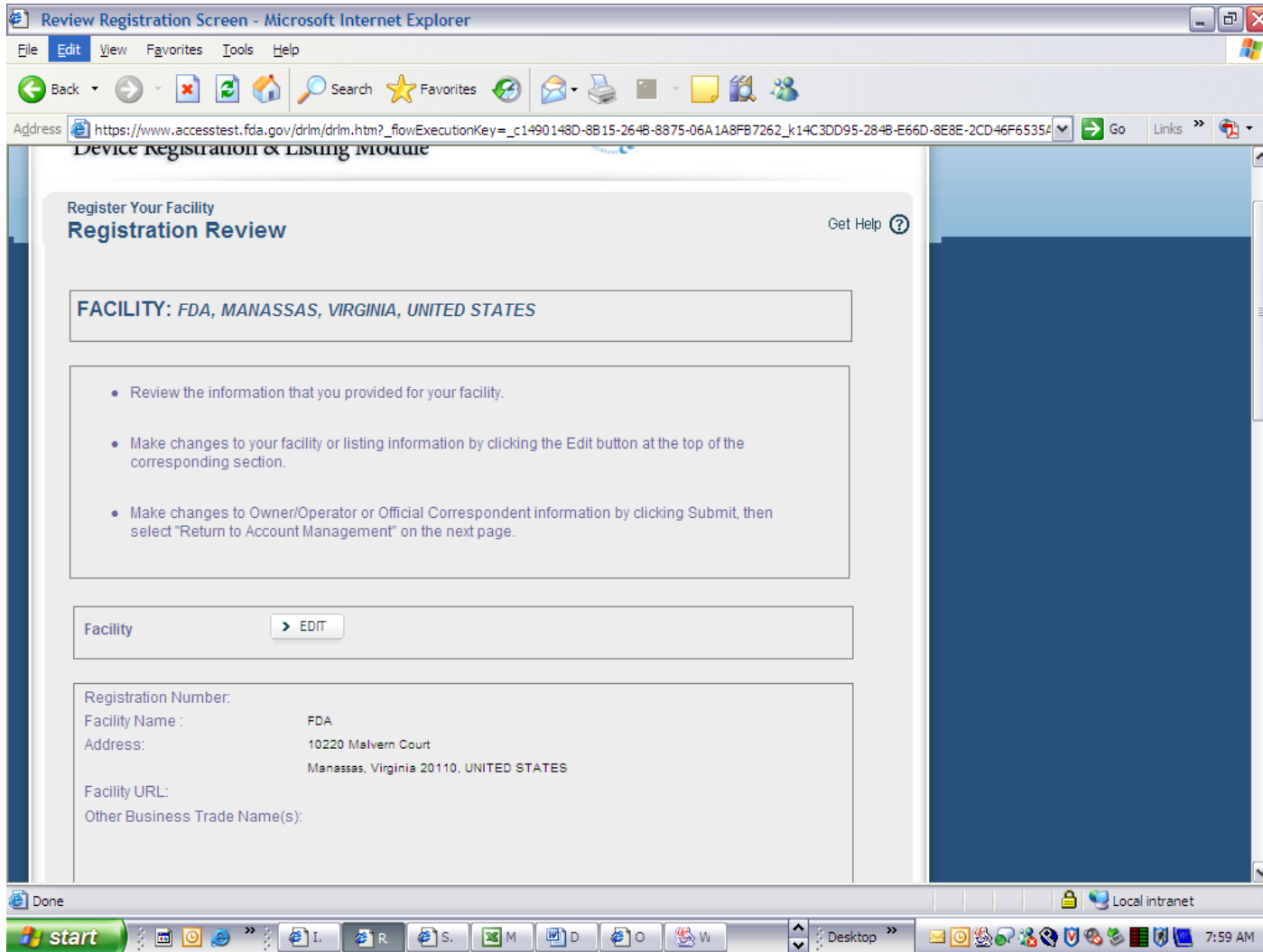
FACILITY: FDA, MANASSAS, VIRGINIA, UNITED STATES

- 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
<input type="radio"/>	New Listing	Exempt	EJX	ANCHOR, PREFORMED	Manufacture Medical Device	Aome

Done Local intranet

start Desktop 7:58 AM



Review Registration Screen - Microsoft Internet Explorer

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Official Correspondent Information > EDIT

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

Device Listings > EDIT

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

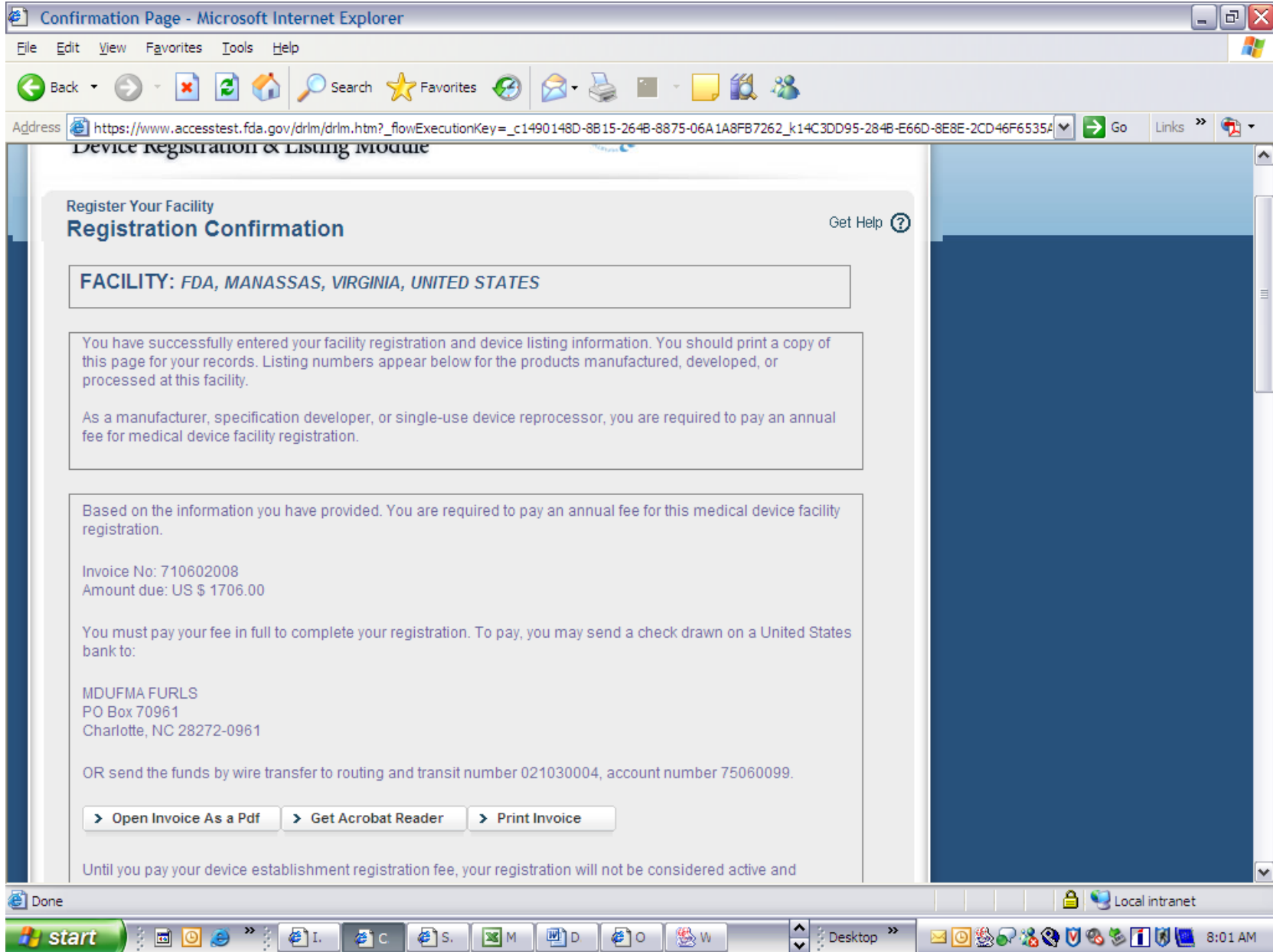
Certification Statement

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.accessgdb.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 reqlist@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 I. C S. M D O W Desktop 8:02 AM

Confirmation Page - Microsoft Internet Explorer

File Edit View Favorites Tools Help

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Address https://www.access.gpo.gov/drlm/drlm.htm?_flowExecutionKey=_c1490148D-8B15-264B-8875-06A1A8FB7262_k14C3DD95-284B-E66D-8E8E-2CD46F6535A Go Links

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

Contact Name: Testsubaccount test
 Company: test
 Address: 20 Main Street
 Manassas, VA 20110, UNITED STATES
 Telephone: 240-2780840
 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

start I. C S. M D O W Desktop 8:02 AM