



# ATTENTION

## Returning FDA Industry Systems Device Registration and Listing Module Users

**Effective July 1, 2016**

The Device Registration and Listing Module of the FDA Unified Registration and Listing System (FURLS) has been modernized with a new look and feel to provide users with the most productive and expeditious experience possible. While the layout and design have changed, users will notice that all the information required and processes remain the same. All existing capabilities are available under the new and improved format.

Users will continue to access DRLM or any of the other FURLS systems via the [FDA Industry Systems home page](#). Please contact the FURLS Help Desk with any questions regarding the updated format ([reglist@cdrh.fda.gov](mailto:reglist@cdrh.fda.gov) or call 301-796-7400, Option 1).

The sections below provide brief examples of the following capabilities:

- [Welcome/Home Page](#)
- [Address Information Interface](#)
- [Making selections in lists \(Sort and Filter\) interfaces](#)
- [Product Activities interface](#)



## Welcome/Home Page

On the DRLM Welcome/Home page, users can complete any DRLM activity by choosing the appropriate Main Menu option from the left navigation bar rather than a menu on a separate screen.

Existing DRLM 'Main Menu' interface: \*

**DRLM**  
Device Registration & Listing Module

FURLS HOME  
DRLM HOME

DRLM Main Menu Get Help ?

**Important Notice:** You must visit the [FDA User Fee website](#) and pay for your facility prior to registering. If you 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:** All establishments must pay the annual registration fee prior to registering or re-registering.

- [Annual Registration](#)  
(Annual Review of Device Registration and Listing Information)
- [View Your Registration and Listing Information](#)
- [Download Your Listing Information](#)
- [Change Registration Information for a Facility](#)
- [Cancel, Deactivate, or Reactivate a Facility Registration](#)
- [Change the Official Correspondent for a Facility](#)
- [Register a New Medical Device Facility](#)
- [Transfer Ownership of a Facility \(Report Purchase\)](#)
- Create Listings for Medical Devices
- [Change, Deactivate, or Reactivate Listings](#)
- [Add/Replace Proprietary Names or Importers to Listings](#)

\*All 'Existing' pages are valid till June 30, 2016



Updated DRLM 'Main Menu' Options on the Left Navigation Bar:

The screenshot displays the DRLM (Device Registration & Listing Module) navigation bar. At the top left is the FDA FURLS logo. To its right, the text reads "DRLM" in a large font, with "Device Registration & Listing Module" below it. Below the header, a "DRLM Home" button is visible. The main navigation menu is organized into four expandable sections, each with a downward arrow:

- Annual Registration**
  - Annual Registration
- Facility Registration**
  - Register a New Medical Device Facility
  - Change Registration Information for a Facility
  - Cancel, Deactivate, or Reactivate a Facility Registration
  - View Your Registration and Listing Information
- Facility Ownership**
  - Change the Official Correspondent for a Facility
  - Transfer Ownership of a Facility (Report Purchase)
- Medical Device Listings**
  - Create Listings for Medical Devices
  - Download Your Listing Information
  - Change, Deactivate, or Reactivate Listings
  - Add/Replace Proprietary Names or Importers to Listings

The screen captures displayed should be considered representative of the final changes



Updated DRLM 'Home Page' interface:

The screenshot shows the DRLM Home Page interface. At the top left is the FDA FURLS logo. The main header reads "DRLM Device Registration & Listing Module". Below the header is a navigation menu with four main categories: Annual Registration, Facility Registration, Facility Ownership, and Medical Device Listings. Each category has a dropdown arrow and a list of sub-links. To the right of the menu is a yellow box containing an "Important Notice" and "Who Must Pay" information. Below that is a white box titled "Important Messages" containing several paragraphs of text, including a "NEW" announcement about updated registration requirements and information about the FDA Safety and Innovation Act (FDASIA).

**Annual Registration** ▾

- Annual Registration

**Facility Registration** ▾

- Register a New Medical Device Facility
- Change Registration Information for a Facility
- Cancel, Deactivate, or Reactivate a Facility Registration
- View Your Registration and Listing Information

**Facility Ownership** ▾

- Change the Official Correspondent for a Facility
- Transfer Ownership of a Facility (Report Purchase)

**Medical Device Listings** ▾

- Create Listings for Medical Devices
- Download Your Listing Information
- Change, Deactivate, or Reactivate Listings
- Add/Replace Proprietary Names or Importers to Listings

**Important Notice:** You must visit the [FDA User Fee website](#) and pay for your facility prior to registering. If you 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:** All establishments must pay the annual registration fee prior to registering or re-registering.

**Important Messages**

**NEW:** The CDRH Learn Device Establishment Registration and Listing Course has been updated with the current registration and listing requirements. Please visit this website <http://www.fda.gov/Training/CDRHLearn/default.htm> to view the course.

The FDA Safety and Innovation Act (FDASIA) was signed into law on July 9, 2012. This law includes the Medical Device User Fee Amendments of 2012 (MDUFA III) as well as other medical device provisions. MDUFA III mandates that, beginning in Fiscal Year 2013, an annual registration user fee be paid for all types of establishments.

The fee for FY 2016 is \$3,845. There is no reduction in this fee for small businesses or any other groups. For more information about User Fees and MDUFA III see <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/default.htm>

You must pay the fee before registering a new establishment or updating your existing registration(s) and/or listing(s) for FY 2016. If you have not paid the fee, please [visit this website](#). For assistance with paying the fee, please send an email to [userfees@fda.gov](mailto:userfees@fda.gov).

FDA primarily communicates with firms by email. To verify that we have the correct email for your account, please click on the FURLS Home link at the top of this page. Then click on the Edit Account Profile button on the left hand side of your screen.

Please note a new feature has been added: You can now download all of your up-to-date listing information in Excel format. Just click "Download Your Listing Information", which is the third choice on the DRLM Main Menu.

The screen captures displayed should be considered representative of the final changes.



## Entering Address Information

When registering a device facility or updating address information for an existing registration, users will notice certain enhancements that apply uniformly among various elements (e.g., data fields and navigational buttons). All design updates were implemented to enhance user experiences and ensure efficient usability throughout the application.

Existing DRLM 'Address Information' interface:

**DRLM**  
Device Registration & Listing Module

Register Your Facility  
**Location Information**

Get Help ?

**Register Your Facility**

Fields marked with an asterisk (\*) are required.

Establishment Information  Same as Owner/Operator  Same as Official Correspondent

Choose Country/Area where Facility is Located:\* --Please Select--

Facility Name:\*

Address Line 1:\*

Address Line 2:

Zip Code:\*

City:\*

State:\*

Phone: Country Code: Area/City Code: Phone Number: Extension:

Fax: Country Code: Area/City Code: Fax Number:

DUNS Number:  
(Enter only the 9-digit number, no dashes or other characters)

Click box if this establishment is located in a foreign trade zone:

Facility URL:

Other Business Trade Name(s): > remove

> Add More Trade Names:

< CLEAR < BACK > SAVE & EXIT > CONTINUE REGISTRATION



Updated DRLM 'Address Information' interface:

The screen captures displayed should be considered representative of the final changes.



## Making Selections in Lists (Sort and Filter)

As seen in the Annual Registration and Add New Product option, DRLM now contains unique data tables that provide advanced features such as a wildcard filter option that filters records within the search results. It also features a dropdown selection to allow users to select how many results should be displayed on the page.

Existing DRLM 'Annual Registration' interface:

**DRLM**  
Device Registration & Listing Module

Annual Re-Registration  
**View Registrations** Get Help ?

**Annual Registration Information**

Select the facility to re-register for 2016. You must:

- Review all of the registration and listing information for each facility and make any changes that may be necessary; or,
- Certify that the information for the facility has not changed since it was last updated; or,
- Deactivate the registration if the establishment is no longer in business or is no longer producing medical devices.

**Important Notice:** You must visit the [FDA User Fee website](#) and pay for your facility prior to registering. If you 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. You must pay the annual registration user fee for all transfers of ownership, regardless of whether the previous owner has already paid an annual registration user fee for the current fiscal year.

**Who Must Pay:** All establishments must pay the annual registration fee prior to registering or re-registering. If you have already provided your Payment Confirmation Number (PCN) for the current fiscal year, you do not need to provide your Payment Identification Number (PIN) and PCN again.

Select	Name And Address	Registration/FEI Number
<input type="radio"/>	Test Medical Company 10903 New Hampshire Ave Silver Spring, Maryland, 20903, UNITED STATES	Registration Number Not Yet Assigned



## Updated DRLM 'Annual Registration' interface:

**Annual Registration Information**

Select the facility to re-register for 2016. You must:

- Review all of the registration and listing information for each facility and make any changes that may be necessary; or,
- Certify that the information for the facility has not changed since it was last updated; or,
- Deactivate the registration if the establishment is no longer in business or is no longer producing medical devices.

**Important Notice:** You must visit the [FDA User Fee website](#) and pay for your facility prior to registering. If you 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. You must pay the annual registration user fee for all transfers of ownership, regardless of whether the previous owner has already paid an annual registration user fee for the current fiscal year.

**Who Must Pay:** All establishments must pay the annual registration fee prior to registering or re-registering. If you have already registered for the current fiscal year, you do not need to provide your Payment Identification Number (PIN) and PCN again.

**Facility List**

Select the facility registration you are updating.

Show  entries ← ↓ Filter:  [Clear Sort and Filter](#) →

Name and Address	Status	Registration/FEI Number	Action
Test Company 409 W Side Dr Gaithersburg, Maryland, 20878, UNITED STATES	Active	7816818164/7816818164	<a href="#">✎</a> <a href="#">✖</a>

Showing 1 to 1 of 1 entries

The screen captures displayed should be considered representative of the final changes.



Existing DRLM 'List of Product Codes' interface:

## DRLM

Device Registration & Listing Module

FURLS HOME  
DRLM HOME

**Create a New Device Listing** Get Help ?

- 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 and identified the type(s) of combination product(s) this device is a part of, click Continue.

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

> FILTER
> CLEAR FILTER

If an exempt product code appears with the selection box grayed out and not selectable, please check to make sure you do not already have a listing for that product code. If you do have an exempt listing for the product code, you must return to the main menu and select Change, Deactivate, or Reactivate Listings, and add any new information to your existing listing.

Displaying Page 1 of 588

	Medical Specialty	Product Code	Device/Product Name	Class	Premarket Submission Required
<input type="radio"/>	CLINICAL CHEMISTRY	CFG	OIL EMULSION/THYMOLPHTHALEIN (TITRIMETRIC), LIPASE	1	510(k) exempt
<input type="radio"/>	CLINICAL CHEMISTRY	CHI	LIPASE-ESTERASE, ENZYMATIC, PHOTOMETRIC, LIPASE	1	510(k) exempt
<input type="radio"/>	CLINICAL CHEMISTRY	CET	OLIVE OIL EMULSION (TURBIDIMETRIC), LIPASE	1	510(k) exempt
<input type="radio"/>	CLINICAL CHEMISTRY	CFD	SULFOPHOSPHOVANILLIN, COLORIMETRY, TOTAL LIPIDS	1	510(k) exempt
<input type="radio"/>	CLINICAL CHEMISTRY	CFB	CHROMATOGRAPHIC DERIVATIVE, TOTAL LIPIDS	1	510(k) exempt
<input type="radio"/>	CLINICAL CHEMISTRY	JQI	ROTATING DISC, PLASMA VISCOMETRY	1	510(k) exempt
<input type="radio"/>	CLINICAL CHEMISTRY	JHN	TURBIDIMETRIC METHOD, LIPOPROTEINS	1	510(k) exempt
<input type="radio"/>	CLINICAL CHEMISTRY	JHL	MICRODENSITOMETRY METHOD, LIPOPROTEINS	1	510(k) exempt
<input type="radio"/>	CLINICAL CHEMISTRY	MRR	SYSTEM, TEST, LOW DENSITY, LIPOPROTEIN	1	510(k) exempt
<input type="radio"/>	CLINICAL CHEMISTRY	MSJ	APOLIPOPROTEINS	1	510(k) exempt

>> Next

---

< BACK
< CANCEL - RETURN to MAIN MENU
> SAVE & EXIT
> CONTINUE



Updated DRLM 'List of Product Codes' interface:

**Annual Registration**

- Annual Registration

**Facility Registration**

- Register a New Medical Device Facility
- Change Registration Information for a Facility**
- Cancel, Deactivate, or Reactivate a Facility Registration
- View Your Registration and Listing Information

**Facility Ownership**

- Change the Official Correspondent for a Facility
- Transfer Ownership of a Facility (Report Purchase)

**Medical Device Listings**

- Create Listings for Medical Devices
- Download Your Listing Information
- Change, Deactivate, or Reactivate Listings
- Add/Replace Proprietary Names or Importers to Listings

DRLM Home > Change Registration information for a Facility

Facility: XYZ CHEMICALS, Laurel, Maryland, UNITED STATES

### Add New Product

#### View Listing Product Codes

If an exempt product code appears with the selection box grayed out and not selectable, please check to make sure you do not already have a listing for that product code. If you do have an exempt listing for the product code, you must return to the main menu and select Change, Deactivate, or Reactivate Listings, and add any new information to your existing listing.

Select Product Code(s)

Show 10 entries Filter: [Clear Sort and Filter](#)

Select	Medical Specialty	Product Code	Device/Product Name	Class	Premarket Submission Required
<input type="checkbox"/>	ANESTHESIOLOGY	BSZ	Gas-machine, anesthesia	2	510(k)
<input type="checkbox"/>	ANESTHESIOLOGY	MRO	APPARATUS, NITRIC OXIDE, BACKUP DELIVERY	2	510(k)
<input type="checkbox"/>	ANESTHESIOLOGY	MRN	APPARATUS, NITRIC OXIDE DELIVERY	2	510(k)
<input type="checkbox"/>	ANESTHESIOLOGY	CCT	APPLICATOR (LARYNGO-TRACHEAL), TOPICAL ANESTHESIA	2	510(k)
<input type="checkbox"/>	ANESTHESIOLOGY	CCO	Bed, rocking, breathing assist	2	510(k) exempt
<input type="checkbox"/>	ANESTHESIOLOGY	BYO	BOTTLE, BLOW	1	510(k) exempt
<input type="checkbox"/>	ANESTHESIOLOGY	CAI	Circuit, breathing (w connector, adaptor, y piece)	1	510(k) exempt
<input type="checkbox"/>	ANESTHESIOLOGY	CAG	Circulator, breathing-circuit	2	510(k)
<input type="checkbox"/>	ANESTHESIOLOGY	BZE	HEATER, BREATHING SYSTEM W/WO CONTROLLER (NOT HUMIDIFIER OR NEBULIZER)	2	510(k)
<input type="checkbox"/>	ANESTHESIOLOGY	JAY	SUPPORT, BREATHING TUBE	1	510(k) exempt

Showing 1 to 10 of 5,881 entries

Previous 1 2 3 4 5 ... 589 Next

< Previous Next >

The screen captures displayed should be considered representative of the final changes.



## Updated Product Activities Interface

The user interface that allows for a Registration to link an activity related to a product associated with the facility has been revamped. It now features a new user friendly table with 'Select Activities for Listings' column, with a dropdown menu that provides options to users to link activities performed by the product in the facility.

Existing DRLM 'Select Activities for Listing(s)' interface:

**DRLM**  
Device Registration & Listing Module

Change Registration Status  
**Select Activities for Listing(s)**

FACILITY: [redacted], FRANCE

Listing: D049441 PERCUSSOR, POWERED-ELECTRIC

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
- Complaint File Establishment per 21 CFR 820.198
- Foreign Private Label Distributor

**Important Notice:** You must visit the [FDA User Fee website](#) and pay for your facility prior to registering. If you have not yet received your Payment Confirmation Number (PCN), you will not be able to register your facility or save any information you have entered and will need to return and re-enter all information for the facility.

Listing: D049444 PERCUSSOR, POWERED-ELECTRIC

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
- Complaint File Establishment per 21 CFR 820.198
- Foreign Private Label Distributor

**Important Notice:** You must visit the [FDA User Fee website](#) and pay for your facility prior to registering. If you have not yet received your Payment Confirmation Number (PCN), you will not be able to register your facility or save any information you have entered and will need to return and re-enter all information for the facility.

< BACK    < CANCEL - RETURN to MAIN MENU    > CONTINUE



Updated DRLM 'Select Activities for Listing(s)' interface:

The screenshot displays the DRLM 'Select Activities for Listing(s)' interface. The main header reads 'DRLM Device Registration & Listing Module'. The central area is titled 'Select Activities & Add Proprietary Names' and shows a facility: 'TEST 12\_30\_0219, Rockville, Maryland, UNITED STATES'. A yellow instruction box states: 'Please provide at least one Proprietary Name for each listing by clicking in Actions column. Please select all activities related to this device that are performed at your facility in Select Activities for Listings column.'

Listing Number	Device Name(s)	Select Activities for Listings	Actions
D238848	Endoscopic retrograde cholangiopancreatography (ERCP) cannula	2 selected	
D238847	Endoscopic grasping/cutting instrument, non-powered	4 selected	

A dropdown menu is open for the second listing, showing the following activity options:

- Manufacture Medical Device
- Develop Specifications But Do Not Manufacture At This Facility
- Manufacture Medical Device for Another Party (Contract Manufacture)
- Sterilize Medical Device for Another Party (Contract Sterilizer)
- Reprocess Single-Use Device
- Repack or Relabel Medical Device
- Remanufacture Medical Device
- Manufacture Device in the United States for Export Only
- Complaint File Establishment per 21 CFR 820.198

The screen captures displayed should be considered representative of the final changes.