

How to Register and List

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General Information

The Food and Drug Administration Amendments Act (FDAAA) of 2007 requires that all registration and listing information (Annual, Initial or Updates) be submitted electronically unless FDA grants a [waiver](#).

The registration of a medical device establishment is a two-step process. First you must pay the annual registration user fee. Once you have paid the fee, you can then complete the registration process. Your registration is not considered complete until you have

- paid your annual registration user fee,
- submitted your registration and listing information electronically, and
- received e-mail notification from FDA that all requirements have been met.



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Paying the Annual Registration Fee

You may pay the annual registration fee electronically at the [Device Facility User Fee \(DFUF\) website](https://userfees.fda.gov/OA_HTML/furls.jsp) (https://userfees.fda.gov/OA_HTML/furls.jsp).

You will receive your Payment Identification Number (PIN) when you make your payment on the DFUF site. You will receive notification of payment confirmation and instructions on obtaining your Payment Confirmation Number (PCN) by email once your payment has cleared. This process can take several days, so be sure to make payment at least a few days before registering.

For additional information, please see [Payment Process \(/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053186.htm\)](#).

Once you have received confirmation of your payment, you can proceed with registering your facility.



Registering Your Facility

Registration and listing information is submitted by using [FDA's Unified Registration and Listing System \(FURLS\)/ Device Registration and Listing Module \(DRLM\) \(https://www.access.fda.gov/oa/\)](#).

Each owner/operator must have an account ID and password to use FURLS. If the owner/operator has designated another person to be the official correspondent, the owner/operator must create a subaccount with a separate account ID and password for the official correspondent.

Firms that are already registered must always use their assigned account ID and password. Never **create a new FURLS account if you already have one**. Creating a new account will prevent you from accessing your current registration information and delay the completion of your correct registration.

If you have any questions on whether you have an established FURLS account, please contact the registration and listing office at [reqlist@cdrh.fda.gov \(mailto:reqlist@cdrh.fda.gov\)](mailto:reqlist@cdrh.fda.gov).

Assistance with resetting your password can be found [on our website \(https://www.access.fda.gov/oa/forgotPasswordflow.htm?execution=e1s1\)](#).



Annual Registration

1. Make payment and obtain the Payment Identification Number (PIN) and the Payment Confirmation Number (PCN) at the [Device Facility User Fee website \(https://userfees.fda.gov/OA_HTML/furls.jsp\)](https://userfees.fda.gov/OA_HTML/furls.jsp).
2. Log on to FURLS (<https://www.access.fda.gov/oa/> (<https://www.access.fda.gov/oa/>)) using your FURLS account ID and password.
If you are performing your annual registration, you already have an account ID and password, DO NOT CREATE A NEW ACCOUNT. Creating a new account will prevent you from accessing your current registration.
3. Select the DRLM button (Device Registration and Listing Module).
4. Select the "Annual Registration" link from the DRLM main menu. You must select the Annual Registration link and complete this process in order for your establishment to be considered registered for the current fiscal year. Selecting this Annual Registration link will also allow you to update your registration and/or listing information.
5. Review the registration information for your establishment and make any updates.
6. Review your listing information and make updates, if needed.
If you are an initial importer, review the list of manufacturers of your imported devices.
If you are a foreign establishment, review your list of known importers for each of your exported devices. If this information has not been entered previously, it must be entered during the annual registration period in order to complete registration for the current fiscal year.

7. Certify that all the information is correct and click on the Submit button.
8. When prompted, enter both the PIN and PCN numbers that you received from the Office of Financial Management for your payment of the establishment registration fee. This information must be entered in order for FDA to accept your registration. If you are not prompted for the PIN/PCN numbers, please send an email to [reglist@cdrh.fda.gov \(mailto:reglist@cdrh.fda.gov\)](mailto:reglist@cdrh.fda.gov). Without entering these numbers, your registration is incomplete.
You will receive a confirmation screen. Once you receive the confirmation screen, FDA will consider you registered.
9. If you have any changes to your listings, return to the main menu and select Change, Cancel or Reactivate Listings to update your listing information.

If you have any questions about this process, please email us at [reglist@cdrh.fda.gov \(mailto:reglist@cdrh.fda.gov\)](mailto:reglist@cdrh.fda.gov).



Initial Registration

1. Make payment and obtain the Payment Identification Number (PIN) and the Payment Confirmation Number (PCN) at the [Device Facility User Fee website \(https://userfees.fda.gov/OA_HTML/furls.jsp\)](https://userfees.fda.gov/OA_HTML/furls.jsp).
2. Go to FURLS at [https://www.access.fda.gov/oa/ \(https://www.access.fda.gov/oa/\)](https://www.access.fda.gov/oa/).
3. If you have never previously registered a device establishment, you will need to first create a FURLS account for the owner/operator (See Types of FURLS Accounts below). Note: If you already have an account for this owner/operator, you must log on to FURLS using that user ID and password.
4. Once you have set up your FURLS account ID and password, select the DRLM button (Device Registration and Listing Module).
5. Select the link "Register a Medical Device Facility" from the DRLM main menu.
6. If you do not have any existing registrations, you will see a page that asks you to identify any existing owner/operator number or registration number for your establishment. Leave the boxes empty and select "No existing registration or OO number."
7. If you have existing registrations, you will be asked to confirm that the establishment being registered does not already appear in the list that is displayed. If the establishment is already registered, **do not create a duplicate record**. If the establishment does not appear in the list displayed, select "Register a New Facility."
8. The **Owner/Operator** and **Official Correspondent** information that you entered when you created or updated your FURLS account will be displayed. 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. If the information is correct, select "Continue Registration."
9. Enter the required information for your facility and select "Continue Registration."
10. You will be prompted to enter information about the devices that you manufacture, process, distribute or import. Manufacturers, processors and distributors must list all devices produced or processed at each facility. Initial importers (facilities that take first title to a device imported into the United States) must list all manufacturers of the devices they are importing.
 - A. For all facilities **EXCEPT** initial importers:
 1. Create Listings for devices produced or processed at this facility.

2. For each listing, identify whether your product requires premarket notification/approval or is exempt.

Note: If a device requires premarket notification clearance or approval it can ONLY be listed AFTER the premarket submission [510(k), PMA, PDP, HDE] is cleared or approved. If this is your only device listing, please do not register your establishment until after your premarket submission is cleared or approved.
3. If your premarket submission is cleared or approved, you will need to do the following to list your device:
 - Enter the premarket submission number
 - Enter the proprietary name(s)
 - Identify the activities that you perform on or to the device
 If your device is exempt from premarket notification/approval, you will need to do the following:
 - Obtain the product code. You may click [here](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm) (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm>) to find your product code.
 - Leave the premarket submission number blank
 - Enter the product code in the filter box and click on "Filter"
 - Select the radio button next to the product code and click "Continue"
 - Identify the activities that you perform on or to the device
 - Enter the proprietary name(s)

B. For Initial Importers (facilities that take first title to a device imported into the United States):

1. On the "Identify Manufacturers" page, click on the "Search & Add Products" button.
2. Identify the manufacturer by using either its device listing number, establishment registration number, or establishment name and address.
3. On the next page, under the registration information that matches the manufacturer of your devices, select the devices that you are importing and click on the "Add Selected Products" button.

11. Certify that all the information is correct and click on the submit button.

12. When prompted, enter both the PIN and PCN numbers that you received from the Office of Financial Management for your payment of the establishment registration fee. This information must be entered in order for FDA to accept your registration. If you are not prompted for the PIN/PCN numbers, please send an email to reglist@cdrh.fda.gov (<mailto:reglist@cdrh.fda.gov>). Without entering these numbers, your registration is incomplete.

You will receive a confirmation screen. Once you receive the confirmation screen, FDA will consider you registered.

13. If you have any changes to your listings, return to the main menu and select Change, Cancel or Reactivate Listings to update your listing information.



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Listing for Combination Products

- **[Presentation: Listing Combination Products in FURLS/DRLM \(/downloads/MedicalDevices/Device-RegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/UCM303615.pdf\)](#)** (PDF)

Regulatory Policy and Systems Branch
Division of Risk Management Operations
Office of Compliance
Center for Devices and Radiological Health
May 2012

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Downloading your listing information from FURLS

In order to import your listed device into the United States, you'll need to provide the registration number or the owner/operation number as well as the listing number of the device.

Follow the instructions [here \(/downloads/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/UCM570530.pdf\)](#) to download the listing information from FURLS

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Reactivating or Deactivating a Registration

To reactivate a registration record that has not previously had payment-related numbers (PIN/PCN) entered for the current fiscal year, you must first pay the user fee by going to the [Device Facility User Fee website \(https://userfees.fda.gov/OA_HTML/furls.jsp\)](#). After payment has been made, and you have obtained both the Payment Identification Number (PIN) and Payment Confirmation Number (PCN), you can proceed with reactivation.

There is no fee associated with deactivating a registration.

Reactivating

1. Log on to FDA Industry Page (FURLS) at [https://www.access.fda.gov/oa/ \(https://www.access.fda.gov/oa/\)](#) with the account ID and password that you previously used to access the establishment registration that you are reactivating.
2. Select the DRLM button (Device Registration and Listing Module).
3. Select the link "Cancel, Deactivate, or Reactivate a Facility Registration."
4. Select the establishment and click on the reactivation button.
5. Unless the establishment is an importer only, you will next be asked to provide device listings. You can either choose from the owner/operator's existing listings or, if not found in the existing listings, you can create a new listing for your device. Importers will be asked to identify the manufacturers of the devices being imported.
6. Certify that all information is correct and click on the submit button.
7. If the current fiscal year payment-related numbers (PIN/PCN) have not previously been entered on the registration record, you will be asked to enter them now.

Deactivating

1. Log on to FDA Industry Page (FURLS) at [https://www.access.fda.gov/oa/ \(https://www.access.fda.gov/oa/\)](#) with the account ID and password that you previously used to access the establishment

registration that you are deactivating.

2. Select the DRLM button (Device Registration and Listing Module).
3. Select the link "Cancel, Deactivate, or Reactivate a Facility Registration".
4. Select the establishment and click on the deactivation button.
5. Certify that you want to deactivate the registration and click on the submit button.



Reactivating or Deactivating a Device Listing

A device listing can only be reactivated for an establishment that has an active registration.

There is no fee associated with deactivating a device listing.

Reactivating

1. Log on to FDA Industry Page (FURLS) at <https://www.access.fda.gov/oaa/> (<https://www.access.fda.gov/oaa/>) with the account ID and password that you previously used to access the establishment registration that you are reactivating.
2. Select the DRLM button (Device Registration and Listing Module).
3. Select the link "Change, Cancel, or Reactivate Listing."
4. Select the listing and click on the reactivation button.
5. Select the establishment that the listing is being reactivated for and click on the continue button.
6. You will be asked to identify the activity associated with the device. You will also be asked to identify the proprietary names.
7. Certify that all information is correct and click on the submit button.

Deactivating

1. Log on to FDA Industry Page (FURLS) at <https://www.access.fda.gov/oaa/> (<https://www.access.fda.gov/oaa/>) with the account ID and password that you previously used to access the establishment registration that you are deactivating.
2. Select the DRLM button (Device Registration and Listing Module).
3. Select the link "Change, Cancel, or Reactivate Listing."
4. Select the listing and click on the deactivation button.
5. Certify that you want to deactivate the listing and click on the submit button.



Types of FURLS Accounts

There are two types of accounts in FURLS: owner/operator and official correspondent:

Owner/Operator

An owner/operator is defined as:

- The corporation, subsidiary, affiliated company, partnership, or proprietor directly responsible for the activities of the registered establishment.

The owner/operator is responsible for creating sub-accounts for any official correspondents he/she identifies.

The owner/operator can:

- Create and update all of the official correspondents' FURLS accounts, including their own account(s)
- Assign official correspondents to registrations
- Create new registrations and listings
- Make changes, updates and cancellations to registrations and listings that they created
- View registration and listing information for the establishments that they created
- View all non-exempt listings belonging to the owner/operator that must be replaced

Official Correspondent

An official correspondent is defined as:

- The person designated by the owner/ operator of an establishment responsible for the annual registration of the establishment and the device listing. The official correspondent also receives correspondence from the FDA involving the owner/operator and any of the firm's establishments.

The official correspondent is responsible for the registration and listing information for each establishment to which he/she is assigned.

The official correspondent can:

- Create new registrations and listings
- Make changes, updates and cancellations to registrations and listings that have been assigned to them
- Add their establishment(s) to listings previously entered for the owner/operator
- View registration and listing information for the establishments which have been created by or assigned to them



Updating Owner/Operator and Official Correspondent Account Information

To update the owner/operator's account information:

1. Log into FURLS using the owner/operator account id and password.
2. Click on "Edit Profile."
3. Select the radio button next to "Account." If you are both the owner/operator and official correspondent for the facility, then you will only see one "Account" when you click on "Edit Profile." If you have designated a person to be the official correspondent for the facility, then you will see "Account" and "Sub-Account" when you click on "Edit Profile."
4. Click on "Modify."

5. Make any necessary changes to the account and click "Submit". Any changes you make to the owner/operator account will be reflected in the Owner/Operator Information for the facility.

To update the official correspondent's account information:

1. The owner/operator must log into FURLS using the owner/operator account id and password.
2. Click on "Edit Profile."
3. Select the radio button next to "Sub-Account" to modify the official correspondent's information.
4. Click on "Modify."
5. Make any necessary changes to the account and click "Submit". The changes you make will automatically be reflected in the official correspondent's information for the facility.

To create new subaccounts for official correspondents:

1. Log into FURLS using the owner/operator account id and password.
2. Click on "Create a Subaccount."
3. Enter the contact information of the official correspondent.
4. Click on "Continue."
5. Review the information and click on "Submit."

(If you change the official correspondent of facility and create a new subaccount for this official correspondent, then you will need to do the following steps to update the official correspondent for the facility)

1. Click on "Device Registration and Listing."
2. From the main menu, select "Change Official Correspondent for a Facility" and click "Continue."
3. Check the box next to the facility that you want to change the official correspondent for and click "Continue."
4. Select the box next to the new official correspondent and click on "Continue."
5. Review the change and click on "Submit."



Updating Registration and Listing Information

1. Updates to Registration and Listing information can be done at any time.
2. If your establishment has not already paid the current year user fee, you must first pay the user fee and obtain the Payment Identification Number (PIN) and the Payment Confirmation Number (PCN) at the **[Device Facility User Fee website \(https://userfees.fda.gov/OA_HTML/furls.jsp\)](https://userfees.fda.gov/OA_HTML/furls.jsp)**.
3. Log on to FURLS **<https://www.access.fda.gov/oa/>** (**<https://www.access.fda.gov/oa/>**) using your FURLS account ID and password.
If you already have an account ID and password, DO NOT CREATE A NEW ACCOUNT. Creating a new account will prevent you from accessing your current registration.
4. Select the DRLM button (Device Registration and Listing Module).
5. Select the "Change Registration" link to update registration information or select the "Change, Cancel or Reactivate Listing" link to update your listing information.
6. Make the necessary changes to your registration or listing information.

7. Review the changes you have made.
8. Certify that all the information is correct and click on the submit button.
9. When prompted, enter both the PIN and PCN numbers that you received from the Office of Financial Management for your payment of the establishment registration fee. This information must be entered in order for FDA to accept your registration. If you are not prompted for the PIN/PCN numbers, please send an email to reglist@cdrh.fda.gov (<mailto:reglist@cdrh.fda.gov>). Without entering these numbers, your registration is incomplete.
You will receive a confirmation screen. Once you receive the confirmation screen, FDA will consider you registered.



Waivers

The law requires that all registration and listing information be submitted electronically unless FDA grants a waiver. To apply for a waiver from submitting your registration and listing information electronically, please submit your request with a complete explanation of why you cannot submit your information electronically to:

Food and Drug Administration
CDRH - Office of Compliance
Registration & Listing
10903 New Hampshire Avenue
Building 66 Room 2621
Silver Spring, MD 20993-0002

Note: If you are granted a waiver, you will still be responsible for the establishment registration fee.



[More in Medical Device Registration and Listing](/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm)

[\(/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm\)](/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm)

[Important Reminders about Registration and Listing](/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm153205.htm)

[\(/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm153205.htm\)](/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm153205.htm)

[Access Electronic Registration](/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053156.htm)

[\(/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053156.htm\)](/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053156.htm)

[Who Must Register, List and Pay the Fee](/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm)

[\(/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm\)](/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm)

[When to Register and List](/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053181.htm)

[\(/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053181.htm\)](/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053181.htm)

[How to Register and List](/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053185.htm)

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