Initial Registration

1. If you are required to pay the establishment registration user fee (See Who Must Register, List & Pay the Fee), you must first visit the Device Facility User Fee website to pay the user fee. Once you make payment and receive confirmation numbers for your payment (PIN/PCN), proceed to the next step.
2. Use your FURLS account ID and password to log on to our site at: https://www.access.fda.gov/oaa/

If you have never submitted any establishment registration before, you will need to first create a FURLS account for the owner/operator. If you already have an account for this owner/operator, you should log on to FURLS using that user ID and password.

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 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

You will also be required to create sub-account for any official correspondents you identify. 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

1. Select the DRLM button (Device Registration and Listing Module). On the next screen that discusses firms that have to pay, bypass that screen if you have already paid or don't have to pay by clicking on Continue.
2. Select the link Register a Medical Device Facility
3. Enter information about your facility
4. Create Listings for devices produced or processed at this facility (note – not all facilities are required to list devices. See Who Must Register, List and Pay the Fee)

For each listing, you will need to identify whether your product requires premarket notification/approval or is exempt.

If your device requires premarket notification clearance or approval, you will have to wait until your premarket submission [510(k), PMA, etc.] is cleared or approved to list the device.

Once 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 names
- Identify the activities that you perform on or to the devices

If your device is exempt from premarket notification/approval you will need to do the following:

- Identify the product code (prior to logging into FURLS)
- 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 devices
- Enter the proprietary names

If you are prompted to enter payment confirmation numbers (PIN/PCN), you must enter this information for FDA to accept your registration. Without these numbers (if prompted), your registration is incomplete and you will have to enter your information again. Your registration is not considered complete until you have paid your registration user fee (if required to do so), submitted your information electronically, and have received notification from FDA that all requirements have been met.