

## How to Identify FDA-Registered Reprocessors of Single-Use Devices

The U.S. Food and Drug Administration (FDA) maintains a database on their website that can be used to identify FDA-registered reprocessors of single-use devices. This database is called the Establishment Registration & Device Listing database and it can be accessed using the link below:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm>

### Step One:

Locate the “Establishment Type” field. The red oval on the screen shot below highlights where to find it.

The screenshot shows a web browser window displaying the FDA's Establishment Registration & Device Listing search interface. The browser's address bar shows the URL: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm>. The page header includes the U.S. Department of Health & Human Services logo and the FDA logo. The main heading is "Establishment Registration & Device Listing". Below this, there is a "Search Registration & Listing Database" section with a "Choose one or more search parameters and select search" instruction. The search parameters are organized into two columns. The first column includes fields for "Establishment Name", "Registration Number", "Owner/Operator Name", "Owner/Operator Number", and "Establishment Type". The second column includes fields for "Classification Name", "Proprietary Name", "Product Code", "Establishment State (U.S.)", and "Establishment Country". The "Establishment Type" field is highlighted with a red oval. At the bottom of the search section, there is a "Sort by" dropdown menu, a "Search" button, a "Clear" button, and a "Records per Report Page" dropdown menu set to "5".

## Step Two:

Select the drop-down menu by clicking on the down arrow next to the “Establishment Type” field. The red arrow on the screen shot below highlights where to find it. Select “Reprocessor of Single Use Devices” from the options on the drop-down menu. The green oval below highlights where to find it.

Establishment Registration & Device Listing

510(k) | Registration & Listing | Adverse Events | Recalls | PMA | Classification | Standards  
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA

Search Registration & Listing Database [Help](#) | [Download Files](#) | [More About Registration & Listing](#)

Choose one or more search parameters and select search

Establishment Name	<input type="text"/>	Classification Name	<input type="text"/>
Registration Number	<input type="text"/>	Proprietary Name	<input type="text"/>
Owner/Operator Name	<input type="text"/>	Product Code	<input type="text"/>
Owner/Operator Number	<input type="text"/>	Establishment State (U.S.)	<input type="text"/>
Establishment Type	<input type="text"/>	Establishment Country	<input type="text"/>

Contract Manufacturer  
Contract Sterilizer  
Manufacturer  
Non-US Exporter  
Remanufacture  
Repackager/Relabeler  
Reprocessor of Single Use Devices  
Specification Developer  
U.S. Manufacturer of Export Only Devices  
Initial Distributor/Importer

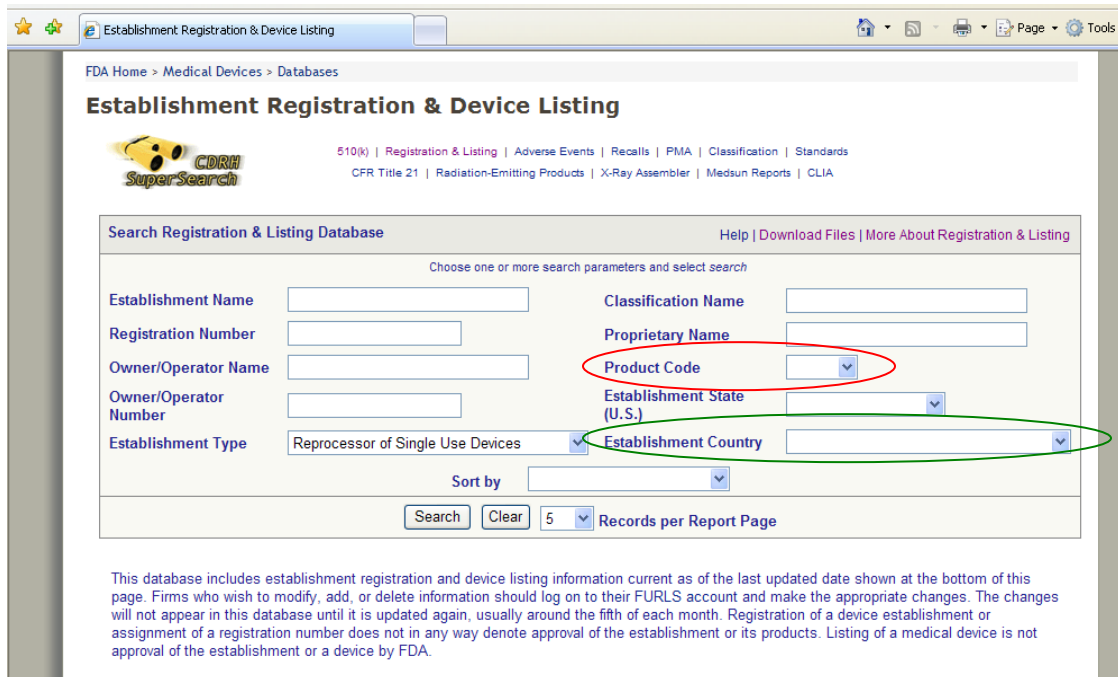
Records per Report Page

This database includes only those establishments that have been assigned a registration approval of the establishment. Firms who wish to be included in this database must submit a request for registration approval. The database is updated current as of the last updated date shown at the bottom of this page. Firms who wish to make changes to their FURLS account and make the appropriate changes. The changes will be reflected in the database within five business days of the date of the change. Registration of a device establishment or listing of a medical device is not required for the establishment or its products. Listing of a medical device is not required for the establishment or its products.

### Step Three:

If no additional limits are set, the search will return all registered reproprocessors of single-use devices. If desired, you may narrow your search in several ways. For example, it may be helpful to limit your search by:

- Product code (see red oval below). Examples of FDA product codes for selected single-use devices are included on the last two pages of these instructions.
- Establishment country (see green oval below)



The screenshot shows the FDA's "Establishment Registration & Device Listing" search interface. The page title is "Establishment Registration & Device Listing". Below the title, there is a navigation bar with links: "510(k) | Registration & Listing | Adverse Events | Recalls | PMA | Classification | Standards | CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA".

The main search area is titled "Search Registration & Listing Database". It includes a "Help | Download Files | More About Registration & Listing" link. Below this, there is a section for "Choose one or more search parameters and select search".

The search parameters are as follows:

- Establishment Name:** Text input field.
- Registration Number:** Text input field.
- Owner/Operator Name:** Text input field.
- Owner/Operator Number:** Text input field.
- Establishment Type:** Dropdown menu with "Reprocessor of Single Use Devices" selected.
- Classification Name:** Text input field.
- Proprietary Name:** Text input field.
- Product Code:** Dropdown menu, highlighted with a red oval.
- Establishment State (U.S.):** Dropdown menu.
- Establishment Country:** Dropdown menu, highlighted with a green oval.

At the bottom of the search area, there is a "Sort by" dropdown menu and a "Search" button. Below the search area, there is a "Clear" button and a "5 Records per Report Page" dropdown menu.

Below the search area, there is a paragraph of text:

This database includes establishment registration and device listing information current as of the last updated date shown at the bottom of this page. Firms who wish to modify, add, or delete information should log on to their FURLS account and make the appropriate changes. The changes will not appear in this database until it is updated again, usually around the fifth of each month. Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Listing of a medical device is not approval of the establishment or a device by FDA.

#### Step Four:

Locate the “Records per Report Page” field and use the drop-down menu to select the number of reports you would like to have displayed on each page of search results. The red oval on the screen shot below highlights where to find it.

The screenshot shows the FDA's Establishment Registration & Device Listing search page. The page includes a navigation bar with links to Home, Food, Drugs, Medical Devices, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, Radiation-Emitting Products, and Tobacco Products. Below the navigation bar is the FDA logo and a search bar. The main heading is "Establishment Registration & Device Listing". A sidebar on the left contains a "CDRH SuperSearch" logo and a list of links: 510(k), Registration & Listing, Adverse Events, Recalls, PMA, Classification, Standards, CFR Title 21, Radiation-Emitting Products, X-Ray Assembler, Medsun Reports, and CLIA. The main content area is titled "Search Registration & Listing Database" and contains a search form. The form has fields for Establishment Name, Registration Number, Owner/Operator Name, Owner/Operator Number, Establishment Type, Classification Name, Proprietary Name, Product Code, Establishment State (U.S.), and Establishment Country. There is also a "Sort by" dropdown menu. At the bottom of the form, there is a "Search" button, a "Clear" button, and a dropdown menu for "Records per Report Page" which is highlighted with a red oval and set to 50. Below the form, there is a disclaimer: "This database includes establishment registration and device listing information current as of the last updated date shown at the bottom of this page. Firms who wish to modify, add, or delete information should log in to their FURLS account and make the appropriate changes. The changes will not appear in this database until it is updated again, usually at the end of each month. Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Listing of a medical device is not..."

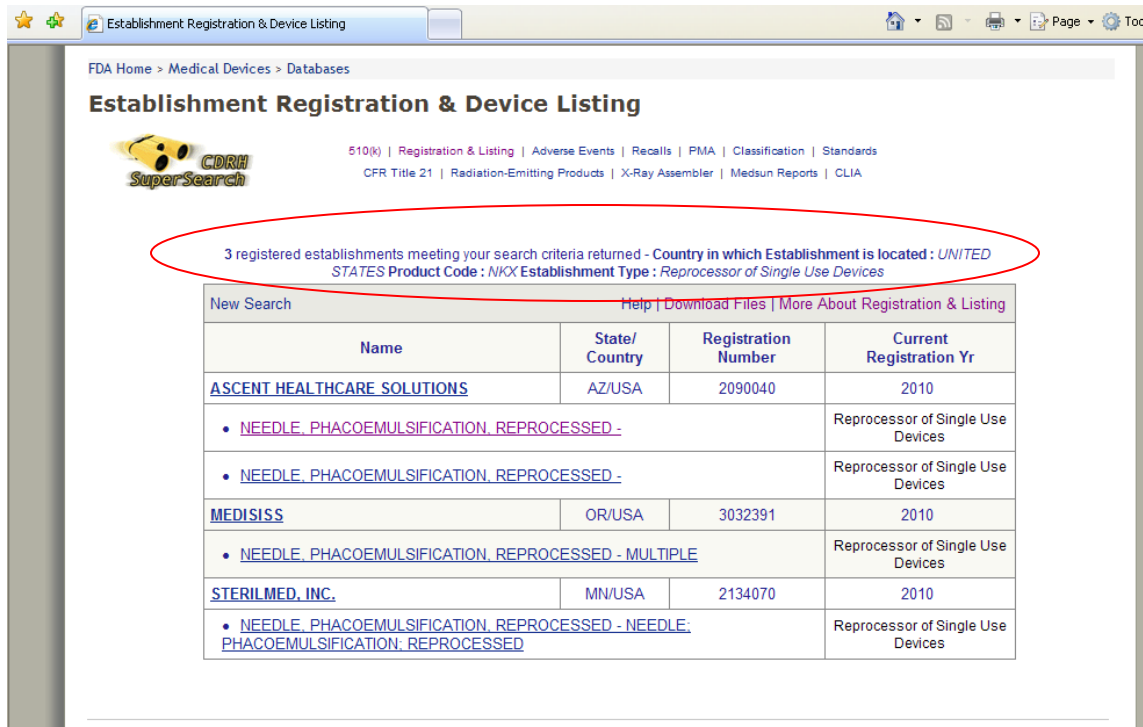
## Step Five:

Click on “Search”. The red oval on the screen shot below highlights where to find it.

The screenshot shows the FDA's Establishment Registration & Device Listing search interface. At the top, there's a navigation bar with the FDA logo and links to various product categories. Below this, a breadcrumb trail indicates the current location: FDA Home > Medical Devices > Databases. The main heading is "Establishment Registration & Device Listing". A "CDRH SuperSearch" logo is visible. A navigation menu lists various links including "510(k)", "Registration & Listing", "Adverse Events", "Recalls", "PMA", "Classification", "Standards", "CFR Title 21", "Radiation-Emitting Products", "X-Ray Assembler", "Medsun Reports", and "CLIA". The search form is titled "Search Registration & Listing Database" and includes a "Help | Download Files | More About Registration & Listing" link. The form contains several input fields: "Establishment Name", "Registration Number", "Owner/Operator Name", "Owner/Operator Number", "Classification Name", "Proprietary Name", "Product Code" (with a dropdown menu showing "NKX"), "Establishment State (U.S.)" (with a dropdown menu), "Establishment Type" (with a dropdown menu showing "Reprocessor of Single Use Devices"), and "Establishment Country" (with a dropdown menu showing "UNITED STATES"). There is a "Sort by" dropdown menu. At the bottom of the form, there is a "Search" button (highlighted with a red oval), a "Clear" button, and a "50" dropdown menu followed by the text "Records per Report Page". A disclaimer at the bottom states: "This database includes establishment registration and device listing information current as of the last updated date shown at the bottom of this page. Firms who wish to modify, add, or delete information should log on to their FURLS account and make the appropriate changes. The changes will not appear in this database until it is updated again, usually around the fifth of each month. Registration of a device establishment or".

## Step Six:

The site will return a list of registered reproprocessors according to the search parameters specified. In this example, the search using product code NKX (for phacoemulsification needles) and establishments in the United States, the following results were obtained: (Please note that the database is routinely updated and the results returned for purposes of this sample search may no longer be valid.)



FDA Home > Medical Devices > Databases

### Establishment Registration & Device Listing

CDRH SuperSearch

510(k) | Registration & Listing | Adverse Events | Recalls | PMA | Classification | Standards  
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA

3 registered establishments meeting your search criteria returned - Country in which Establishment is located: UNITED STATES Product Code: NKX Establishment Type: Reprocessor of Single Use Devices

New Search [Help](#) | [Download Files](#) | [More About Registration & Listing](#)

Name	State/ Country	Registration Number	Current Registration Yr
<a href="#">ASCENT HEALTHCARE SOLUTIONS</a>	AZ/USA	2090040	2010
• <a href="#">NEEDLE, PHACOEMULSIFICATION, REPROCESSED -</a>			Reprocessor of Single Use Devices
• <a href="#">NEEDLE, PHACOEMULSIFICATION, REPROCESSED -</a>			Reprocessor of Single Use Devices
<a href="#">MEDISISS</a>	OR/USA	3032391	2010
• <a href="#">NEEDLE, PHACOEMULSIFICATION, REPROCESSED - MULTIPLE</a>			Reprocessor of Single Use Devices
<a href="#">STERILMED, INC.</a>	MN/USA	2134070	2010
• <a href="#">NEEDLE, PHACOEMULSIFICATION, REPROCESSED - NEEDLE, PHACOEMULSIFICATION, REPROCESSED</a>			Reprocessor of Single Use Devices

## FDA Product Codes for Selected Reprocessed Single-Use Devices

Classification Name	Product Code for Reprocessed Device	Product Code Name for Reprocessed Device
Ear, Nose, and Throat Bur	NLY	ENT High Speed Microdebrider
Ear, Nose, and Throat Bur	NLZ	ENT Diamond Coated Bur
Ear, Nose, Throat Manual Surgical	NLB	Laryngeal, Sinus, Tracheal Trocar
Gastroenterology- Urology Biopsy Instrument	NON	Nonelectric Biopsy Forceps
Ureteral Stone Dislodger	NQT, NQU	Flexible and Basket Stone Dislodger
Introduction/Drainage Catheter and Accessories	NMT	Catheter Needle
Manual Surgical Instrument	NNA	Percutaneous Biopsy Device
Manual Surgical Instrument	NMU	Gastro-Urology Needle
Manual Surgical Instrument	NNC	Aspiration and Injection Needle
Forming/Cutting Clip Instrument	NMN	Forming/Cutting Clip Instrument
Laparoscopic Insufflator	NMI	Laparoscopic Insufflator and Accessories
OB/GYN Specialized Manual Instrument	NMG	Gynecological Biopsy Forceps
Manual Ophthalmic Surgical Instrument	NLA	Ophthalmic Knife
Ultrasonic Surgical Instrument	NLQ	Ultrasonic Scalpel
Anesthesia Conduction Needle	NNH	Anesthetic Conduction Needle (with/without Introducer)
Anesthesia Conduction Needle	NMR	Short Term Spinal Needle
Oximeter	NMD	Tissue Saturation Oximeter
Oximeter	NLF	Oximeter
External Vein Stripper	NLJ	External Vein Stripper
Gastro-Urology Biopsy Instrument	NMX	G-U Biopsy Needle and Needle Set
Gastro-Urology Biopsy Instrument	NLS	Biopsy Instrument
Endoscope and Accessories	NMY	Endoscopic Needle
Endoscope and Accessories	NKZ	Endoilluminator
Endoscope and Accessories	NLM	General and Plastic Surgery Laparoscope
Endoscopic Electrosurgical Unit and Accessories	NLW	Active Urological Electrosurgical Electrode

Endoscopic Electrosurgical Unit and Accessories	NLV	Flexible Suction Coagulator Electrode
Endoscopic Electrosurgical Unit and Accessories	NLU	Electric Biopsy Forceps
Endoscopic Electrosurgical Unit and Accessories	NLT	Flexible Snare
Endoscopic Electrosurgical Unit and Accessories	NLR	Endoscopic (with or without accessories) Electrosurgical Unit
Electrosurgical Cutting and Coagulation Device and Accessories	NUJ	Endoscopic and Laparoscopic Electrosurgical Accessories
Gynecologic Laparoscope and Accessories	NMH	Gynecologic Laparoscope (and Accessories)
Keratome	NKY	Keratome Blade
Phacofragmentation System	NKX	Phacoemulsification Needle
Radionuclide Brachytherapy Source	NMP	Isotope Needle