

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 this link: <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 the FDA's Establishment Registration & Device Listing search page. At the top, there is a navigation bar with the FDA logo and the text "U.S. Food and Drug Administration Protecting and Promoting Your Health". Below this is a search bar with a "SEARCH" button. A horizontal menu contains various categories: Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Tobacco Products.

The main heading is "Establishment Registration & Device Listing". Below it, there are breadcrumb links: FDA Home > Medical Devices > Databases. To the right of the heading are icons for printing, a plus sign, and an email icon.

On the left, a box titled "This database includes:" lists two items: "medical device manufacturers registered with FDA and" and "medical devices listed with FDA". Below this is a note: "Note: Registration of a device establishment, assignment of a registration number, or listing of a medical device does not in any way denote approval of the establishment or its products by FDA." and a link "Learn More...".

The central "Search Database" section contains a form with the following fields:

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

At the bottom of the search form are buttons for "Quick Search", "Clear Form", and "Search".

On the right side, there is a section titled "Other Databases" with a list of links: 510(k)s, De Novo, Medical Device Reports (MAUDE), CDRH FOIA Electronic Reading Room, CFR Title 21, CLIA, Device Classification, Humanitarian Device Exemption, Inspections, Medsun Reports, Premarket Approvals (PMAs), Post-Approval Studies, Postmarket Surveillance Studies, Radiation-Emitting Products, Radiation-Emitting Electronic Products Corrective Actions, Recalls, Standards, Total Product Life Cycle, and X-Ray Assembler.

At the bottom right, there is a box titled "Need to update your information?"

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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.

The screenshot shows the FDA's Establishment Registration & Device Listing page. The page header includes the FDA logo and navigation tabs for various product categories. The main content area is titled "Establishment Registration & Device Listing" and includes a search form with fields for Establishment Name, Owner/Operator Name, Proprietary Name, Product Code, Establishment State, Registration Number, Owner/Operator Number, Classification Device Name, Establishment Type, and Establishment Country. The "Establishment Type" dropdown menu is open, displaying a list of options. The option "Reprocessor of Single Use Devices" is highlighted with a green oval. A red arrow points to the dropdown menu. The page also includes a "Search Database" section with a "Quick Search" button and a "Need to update your information?" section.

U.S. Department of Health & Human Services

U.S. Food and Drug Administration
Protecting and Promoting Your Health

Home Food Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Biologics Animal & Veterinary Cosmetics Tobacco Products

Establishment Registration & Device Listing

FDA Home Medical Devices Databases

This database includes:

- medical device manufacturers registered with FDA and
- medical devices listed with FDA

Note: Registration of a device establishment, assignment of a registration number, or listing of a medical device does not in any way denote approval of the establishment or its products by FDA.

[Learn More...](#)

Search Database Help Download Files

Establishment Name:

Registration Number:

Owner/Operator Name:

Owner/Operator Number:

Proprietary Name:

Classification Device Name:

Product Code:

Establishment Type:

Establishment State (U.S.):

Establishment Country:

[Quick Search](#)

Other Databases

- 510(k)s
- De Novo
- Medical Device Reports (MAUDE)
- CDRH FOIA Electronic Reading Room
- CFR Title 21
- CLIA
- Device Classification
- Humanitarian Device Exemption
- Inspections
- Medsun Reports
- Premarket Approvals (PMAs)
- Post-Approval Studies
- Postmarket Surveillance Studies
- Radiation-Emitting Products
- Radiation-Emitting Electronic Products Corrective Actions
- Recalls
- Standards
- Total Product Life Cycle
- X-Ray Assembler

Need to update your information?

To modify, add, or delete information, log onto your FURLS account.

Note: Changes will appear when the database is updated (usually every Monday).

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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) or Establishment State (U.S.) (see red arrow below)

U.S. Department of Health & Human Services

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FDA U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

SEARCH

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

Establishment Registration & Device Listing

FDA Home > Medical Devices > Databases

This database includes:

- medical device manufacturers registered with FDA and
- medical devices listed with FDA

Note: Registration of a device establishment, assignment of a registration number, or listing of a medical device does not in any way denote approval of the establishment or its products by FDA.
[Learn More...](#)

Search Database Help Download Files

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

Quick Search Clear Form Search

Other Databases

- 510(k)s
- De Novo
- Medical Device Reports (MAUDE)
- CDRH FOIA Electronic Reading Room
- CFR Title 21
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- Humanitarian Device Exemption
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- Premarket Approvals (PMAs)
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- Postmarket Surveillance Studies
- Radiation-Emitting Products
- Radiation-Emitting Electronic Products Corrective Actions
- Recalls
- Standards
- Total Product Life Cycle
- X-Ray Assembler

Need to update your information?

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Step Four:

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 is a navigation bar with the FDA logo and the text "U.S. Food and Drug Administration Protecting and Promoting Your Health". Below this is a search bar with a "SEARCH" button. The main content area is titled "Establishment Registration & Device Listing" and includes a breadcrumb trail: "FDA Home > Medical Devices > Databases".

On the left, a box titled "This database includes:" lists:

- medical device manufacturers registered with FDA and
- medical devices listed with FDA

A note states: "Note: Registration of a device establishment, assignment of a registration number, or listing of a medical device does not in any way denote approval of the establishment or its products by FDA." A link "Learn More..." is provided.

The "Search Database" section contains the following fields:

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

At the bottom of the search section, there are three buttons: "Quick Search", "Clear Form", and "Search". The "Search" button is circled in red.

On the right, a box titled "Other Databases" lists various categories:

- 510(k)s
- De Novo
- Medical Device Reports (MAUDE)
- CDRH FOIA Electronic Reading Room
- CFR Title 21
- CLIA
- Device Classification
- Humanitarian Device Exemption
- Inspections
- Medsun Reports
- Premarket Approvals (PMAs)
- Post-Approval Studies
- Postmarket Surveillance Studies
- Radiation-Emitting Products
- Radiation-Emitting Electronic Products Corrective Actions
- Recalls
- Standards
- Total Product Life Cycle
- X-Ray Assembler

At the bottom right, there is a box titled "Need to update your information?"

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Step Five:

The site will return a list of registered reprocessors 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.)

The screenshot shows the FDA's Establishment Registration & Device Listing search results. The page header includes the U.S. Department of Health & Human Services logo and the FDA logo with the text "U.S. Food and Drug Administration Protecting and Promoting Your Health". Navigation links for "Home", "Food", "Drugs", "Medical Devices", "Radiation-Emitting Products", "Vaccines, Blood & Biologics", "Animal & Veterinary", "Cosmetics", and "Tobacco Products" are visible. The search results section displays the following information:

- 1 to 2 of 2 Results for **Country in which Establishment is located : UNITED STATES**
- Product Code : NKX Establishment Type : Reprocessor of Single Use Devices**
- Results per Page: 10
- New Search

Establishment Name	Registration Number	Current Registration Yr
Medline ReNewal OR/USA	3032391	2016
• Needle, Phacoemulsification, Reprocessed		Reprocessor of Single Use Devices
STERILMED, INC. MN/USA	2134070	2016
• Needle, Phacoemulsification, Reprocessed - Reprocessed Needles		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

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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