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:

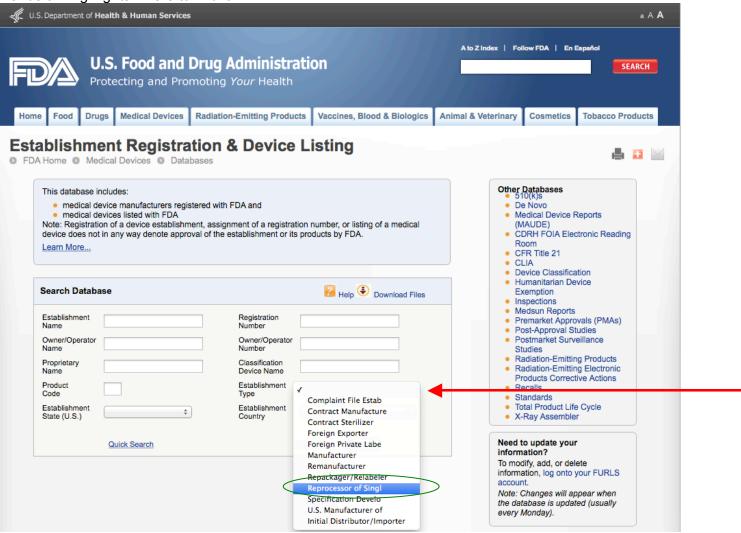
Locate the "Establishment Type" field. The red oval on the screen shot below highlights where to find it.

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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.



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Step Three:

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If no additional limits are set, the search will return all registered reprocessors 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)

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Step Four: Click on "Search". The red oval on the screen shot below highlights where to find it.

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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.)

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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	NUJ	Endoscopic and Laparoscopic Electrosurgical
and Accessories		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