ASC Quality Collaboration

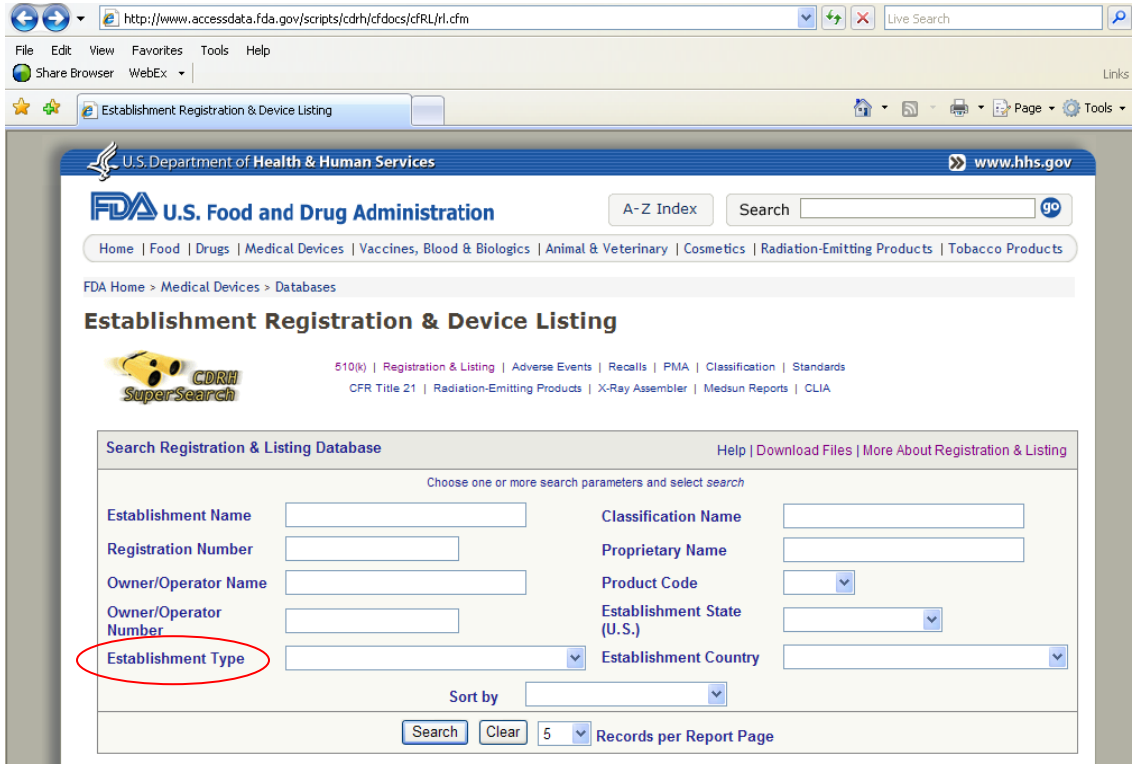
How to Identify FDA-Registered Reprocessors of Single-Use Devices

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:

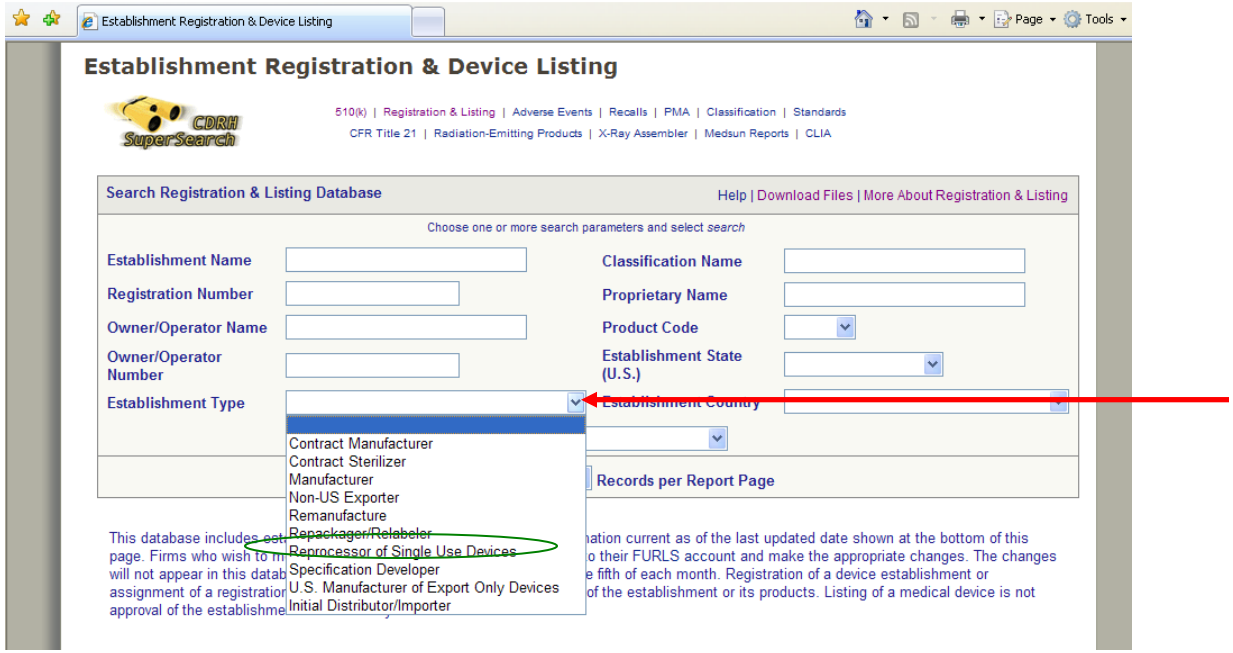
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

Step One:

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



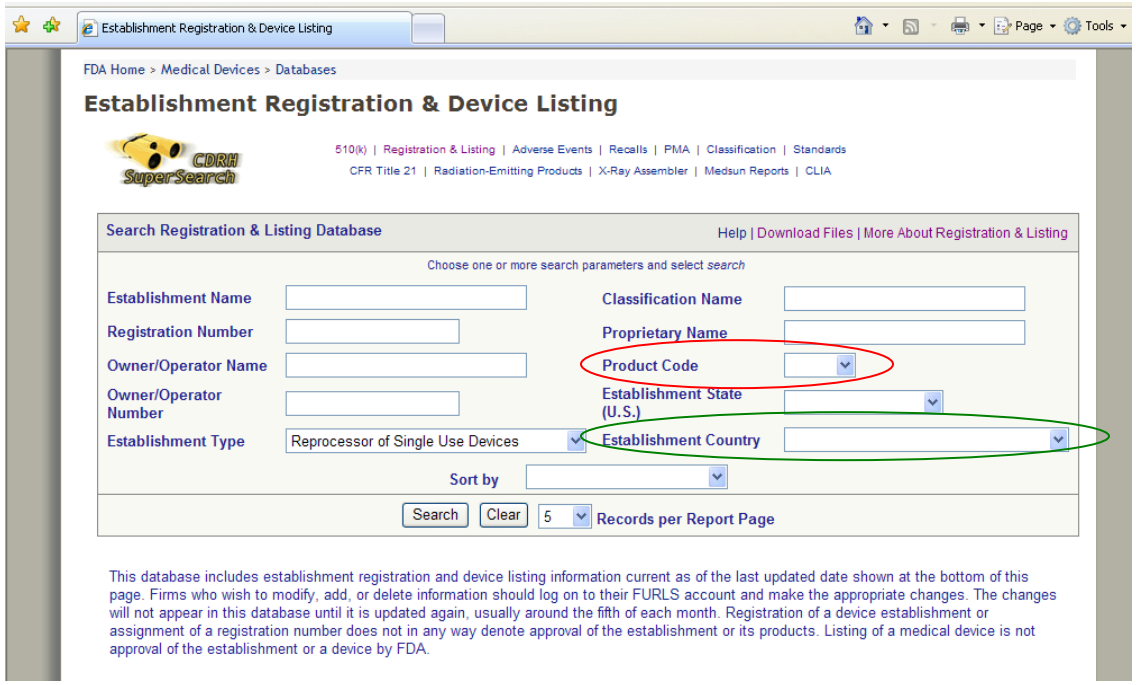
Step Two:
Select the drop-down menu by clicking on the down arrow next to the “Establishment Type” field. The red arrow on the screen shot below highlights where to find it. Select “Reprocessor of Single Use Devices” from the options on the drop-down menu. The green oval below highlights where to find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



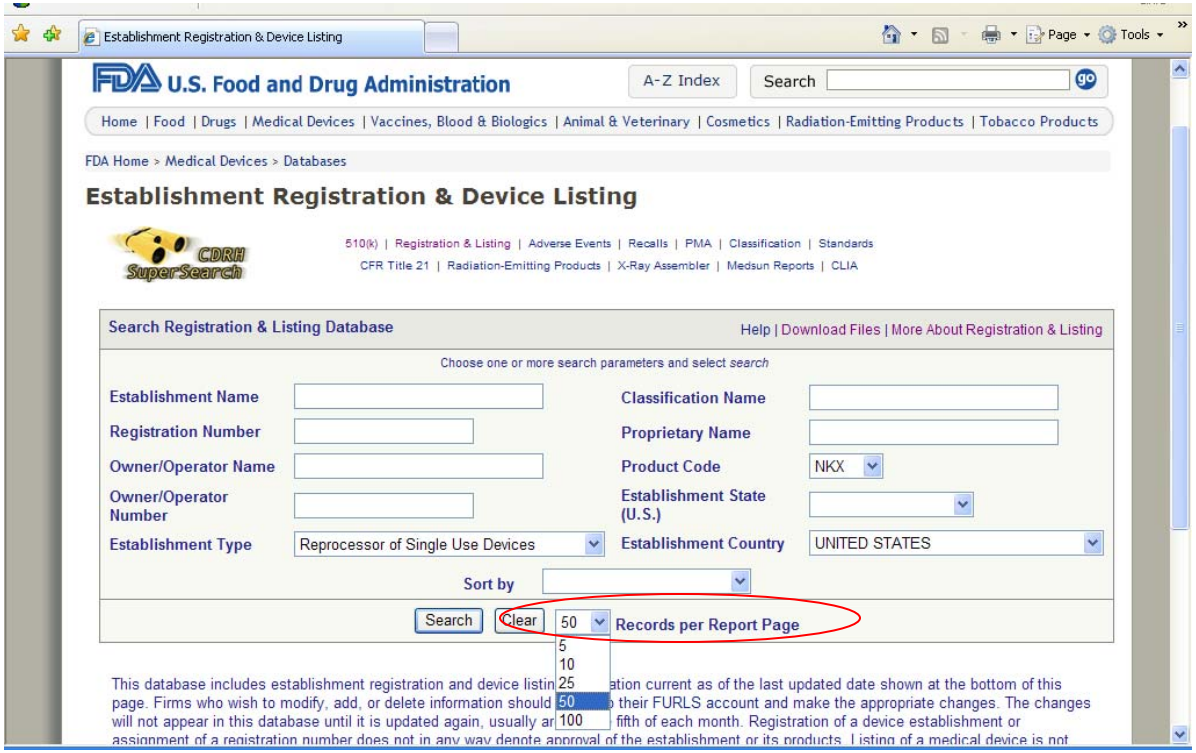
Step Three:

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:

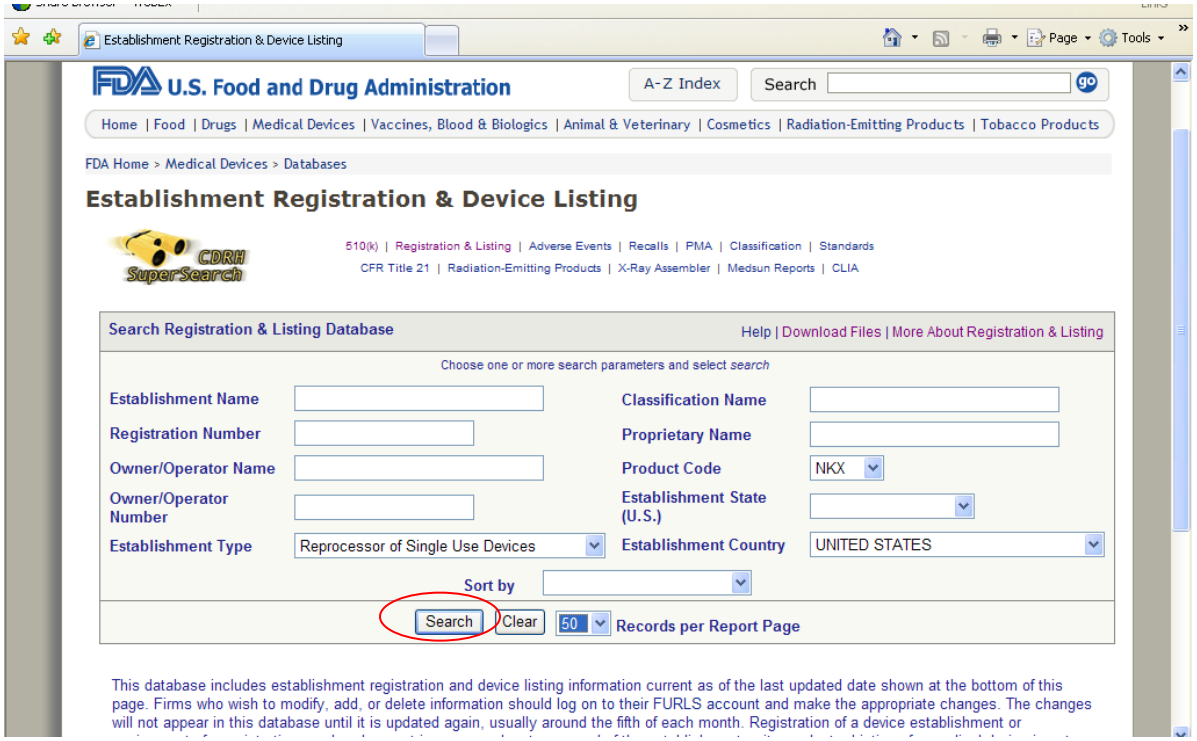
- Product code (see red oval below). Examples of FDA product codes for selected single-use devices are included on the last two pages of these instructions.
- Establishment country (see green oval below)



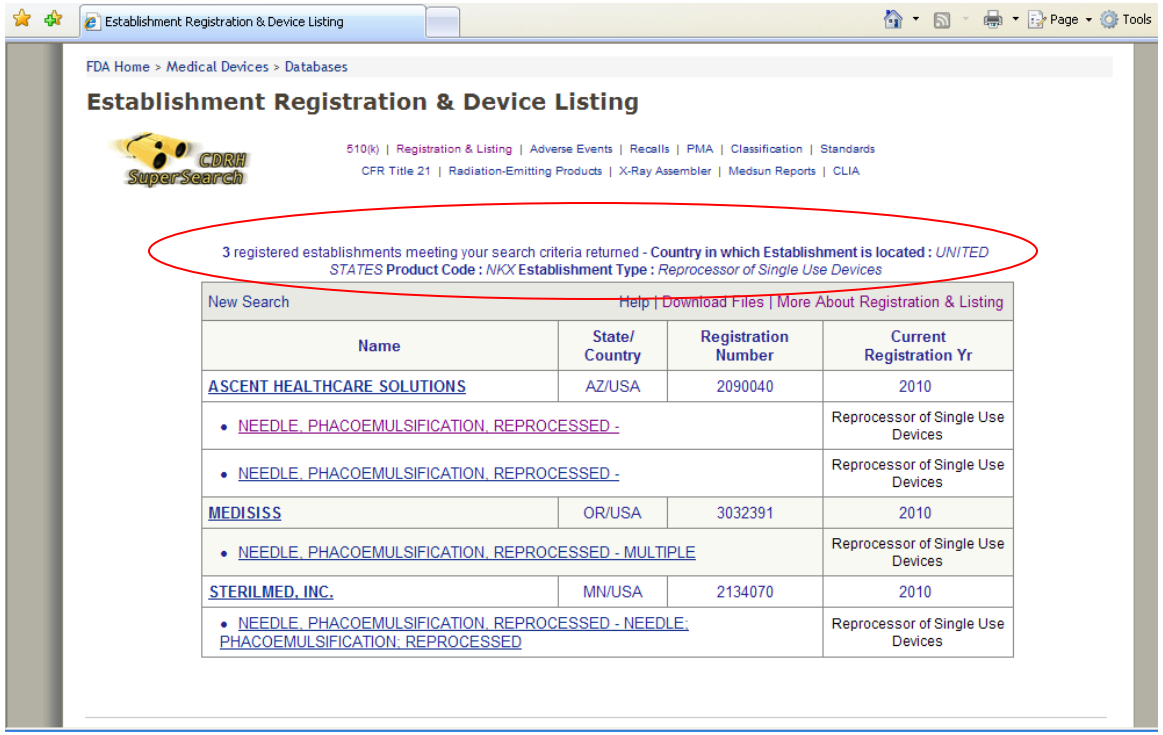
Step Four:
Locate the “Records per Report Page” field and use the drop-down menu to select the number of reports you would like to have displayed on each page of search results. The red oval on the screen shot below highlights where to find it.



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



Step Six:
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.)



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