



This guidance is being provided to assist STERIS Customers to use the FDA website to identify if STERIS has listed a specific medical device with FDA. Because the FDA website does not provide direct traceability to a Customer name or product codes that have been listed, it is possible that a Customer may need more detail from STERIS after going through the steps below. If you require additional assistance, please email questions to Device_Registration@STERIS.com.

<u>Instructions</u>

1. From the list below, locate the Establishment Registration Number for the STERIS Isomedix facility (or facilities) your product is shipped to.

| | Device |
|--------------------------------------|----------------|
| STERIS Facility | Registration # |
| Chester | 1319660 |
| El Paso | 1643817 |
| El Paso 2 | 3009888344 |
| Grand Prairie | 1650907 |
| Groveport | 1526711 |
| Libertyville North (1880 Industrial) | 1450662 |
| Libertyville South (2500 Commerce) | 1424263 |
| Minneapolis | 2183744 |
| Northborough | 1220477 |
| Ontario | 2032098 |
| San Diego | 2032112 |
| Sandy | 1720929 |
| South Plainfield | 2246552 |
| Spartanburg | 1047843 |
| Temecula | 2030624 |
| Vega Alta | 2648623 |
| Whippany | 2245304 |
| Whitby | 9680143 |

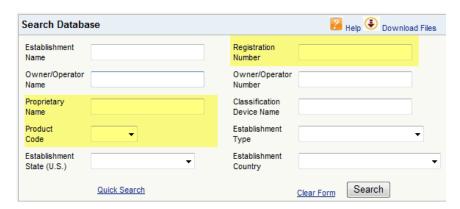
- 2. Have your product specific proprietary name and/or product code (exempt devices) available.
- 3. Go to http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

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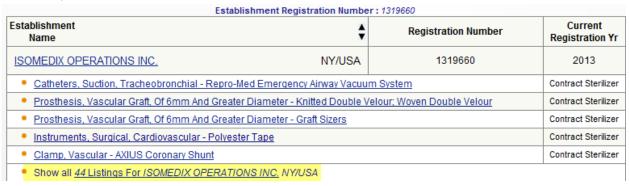


Medical Device Listing FDA Website Guidance

4. Using the information above, complete the FDA highlighted search fields below. Click search.



5. In the search return, click the highlighted last row and to continue to search for your specific device (see example below).



6. In the search return, click on the product that matches your product information (see example below) to display more specifics.



- 7. View product specific information.
- 8. Email Device_Registration@STERIS.com if additional information is required.

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