# Establishment Registration & Device Listing



1 result found for **Owner Operator Number :**
*10044354*

New Search

| Establishment Name | | Registration Number | Current Registration Yr |
|---|---|---|---|
| TROCAR SWEEP LLC | TX/USA | 3010283533 | 2016 |
| • Cannula, Surgical, General & Plastic Surgery - Trocar Sweep | | | Manufacturer |

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| | |
|---|---|
| **Proprietary Name:** | Trocar Sweep |
| **Classification Name:** | CANNULA, SURGICAL, GENERAL & PLASTIC SURGERY |
| **Product Code:** | GEA |
| **Device Class:** | 1 |
| **Regulation Number:** | 878.4800 |
| **Medical Specialty:** | General & Plastic Surgery |
| **Registered Establishment Name:** | TROCAR SWEEP LLC |
| **Registered Establishment Number:** | 3010283533 |
| **Owner/Operator:** | Trocar Sweep LLC |
| **Owner/Operator Number:** | 10044354 |
| **Establishment Operations:** | Manufacturer |

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# Product Classification



| | |
|---|---|
| **Device** | Cannula, Surgical, General & Plastic Surgery |
| **Regulation Description** | Manual surgical instrument for general use. |
| **Regulation Medical Specialty** | General & Plastic Surgery |
| **Review Panel** | General & Plastic Surgery |
| **Product Code** | GEA |
| **Premarket Review** | Office of Device Evaluation (ODE)<br>Division of Surgical Devices (DSD)<br>General Surgery Devices Branch One - Light Based/Laser (GSDB1) |
| **Submission Type** | 510(K) Exempt |
| **Regulation Number** | 878.4800 |
| **Device Class** | 1 |
| **Total Product Life Cycle (TPLC)** | TPLC Product Code Report |
| **GMP Exempt?** | No |

**Note:** FDA has exempted almost all class I devices (with the exception of reserved devices) from the premarket notification requirement, including those devices that were exempted by final regulation published in the *Federal Registers* of December 7, 1994, and January 16, 1996. It is important to confirm the exempt status and any limitations that apply with 21 CFR Parts 862-892. Limitations of device exemptions are covered under 21 CFR XXX.9, where XXX refers to Parts 862-892.

If a manufacturer's device falls into a generic category of exempted class I devices as defined in 21 CFR Parts 862-892, a premarket notification application and fda clearance is not required before marketing the device in the U.S. however, these manufacturers are required to register their establishment. Please see the Device Registration and Listing website for additional information.

| | |
|---|---|
| **Implanted Device?** | No |
| **Life-Sustain/Support Device?** | No |
| **Third Party Review** | Not Third Party Eligible |

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