

K971728

SEP 19 1997

5. 510(k) SUMMARY

A. ADMINISTRATIVE INFORMATION

Manufacturer Identification and Sponsor:

Pioneer Laboratories
375 River Park Circle
Marquette, MI 49855

Establishment Registration Number: 1833824

Official Contact: Burns Severson
Senior Vice President

B. DEVICE IDENTIFICATION

Proprietary Name: Pioneer Elec-Trocar Device

Common Name:

Classification Name and Reference: Device, Electrosurgical, CFR 878.4200

Regulatory Class: II

Device Product Code: GBS

Devices on which substantial equivalence is claimed:

Snyder Hemovac Round Drain with Trocar

Valleylab Footswitching Pencil

ConMed Trogard Universal Trocar

C. DEVICE DESCRIPTION

The Pioneer Laboratories Elec-Trocar is a wound drain placement device. It cuts with radio frequency energy supplied by an electrosurgical generator to create a tunnel from the inside cavity of the wound through the skin. The Elec-Trocar is composed of an insulated wire, a drain tube surrounding the wire, and an exposed cutting tip, which is connected to the wire and positioned at the distal end of the tube. The proximal end of the wire connects to a conventional electrosurgical generator with an adapter. The electrosurgical current is activated with the generator's footswitch controls.

The cutting tip is positioned inside the wound area, and the Elec-Trocar is activated electrically via the footswitch. The cutting tip is advanced through the tissue, toward and through the skin. After the entire hand grip is positioned outside the skin, the wire is detached from the generator and the hand grip is cut off. The insulated wire is then pulled from the drain tube retrograde through the wound, leaving the drain tube in the tissue tunnel.

5. 510(k) SUMMARY (Cont'd)

D. INTENDED USE

The Pioneer Laboratories Elec-Trocar is intended to be used in general surgical procedures to place a wound drain for evacuation of serosanguineous fluid, blood, pus, or other bodily fluids.

E. TECHNOLOGICAL CHARACTERISTICS COMPARED TO PREDICATE DEVICES

The Elec-Trocar and the Snyder Round Drain with Trocar both place silicone or PVC wound drains. The Snyder Drain utilizes a sharp, stainless steel trocar for puncturing a hole through tissue to place the drain, while the Elec-Trocar utilizes a stainless steel blunt tip, powered by electrocautery action (radio frequency energy) from an electrosurgical generator.

The electrosurgical characteristics of the Elec-Trocar are similar to the Valleylab footswitching pencil and the ConMed TroGard. The Elec-Trocar has the same wire terminal connection to the generator as the Valleylab pencil. The Trogard has a stainless steel blunt tip like the Elec-Trocar and is used to cut a tissue tunnel with radio frequency energy.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Mr. Burns Severson
V.P. Regulatory Affairs and Quality Assurance
Pioneer Laboratories
375 River Park Circle
Marquette, Michigan 49855

SEP 19 1997

Re: K971728
Trade Name: Pioneer Elec-Trocar Device
Regulatory Class: II
Product Code: GEI
Dated: August 25, 1997
Received: August 29, 1997

Dear Mr. Severson:

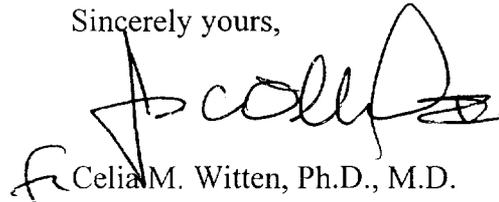
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



375 River Park Circle
Marquette, MI 49855

phone
(906) 226-9909
fax
(906) 226-9932

**PIONEER LABORATORIES
ELEC-TROCAR DEVICE**

INDICATION FOR USE

The device is used in general surgical procedures to place a wound drain by electrocautery action for extraction of serosanguineous fluid, blood, pus, or other bodily fluids.

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K977728

Prescription Use
(Per 21 CFR 801.109)

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