MAY 18 2005

K050957

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510(k) Summary

Special Devices Incorporated

12493 Old Rough and Ready Hwy.

Grass Valley, CA 95945

Telephone 530/273-6763

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Contact Name: Joseph J. Spranza III

March 26, 2005

Trade Name, EuTrochar

Common Name, trocar for installing surgical drains

Name of legally marketed devices.

The Davol Reliavac with PVC Drain, DVL3463

TLS Surgical Drainage System, 7 French Drain Kit

trocar. Catalogue Number 6640.

Description. The EuTrochar is a trocar used for the installation of surgical drains. The EuTrochar has a handle, the "Deployer" to facilitate gripping, to improve accuracy of drain placement and to keep fingers away from the sharp point. Trocars have been used for more than a hundred years to create an incision in soft tissue for surgical drain tubing. Like other drain installation trocars, this instrument is a highly polished stainless steel rod of small diameter, normally 4 to 6mm in diameter and about 160mm long. One end of the rod is very sharply pointed and the other end has a hose barb for affixing tying. The rod is curved between the two ends so that it looks like a giant sailmaker's needle.

Intended Use. The EuTrochar is a trocar used for the installation of surgical drains.

Summary of technological characteristics of the device compared with the predicate devices. Like other drain installation trocars, this instrument is a highly polished stainless steel rod, curved in the middle of the length and having a sharp pointed end and a second end for tubing attachment. Beyond the similarities, there are several differences between the EuTrochar and predicate drain installation trocars. Predicate drain installation trocars have a soft plastic cover over the sharp pointed end. This cover must be removed before use. The surgeon or surgical assistant pulls this plastic cover off. Then, grasping the trocar in his hand or with pliers, the surgeon pushes the point into the area where he wants the drain tubing and forces the predicate trocar from within the surgical incision, through soft tissue to the outside. When the sharp pointed end emerges from the outside tissue, the surgeon typically grasps the emerging pointed end using pliers. He then pulls the trocar through the tissue flap and with it, on the trailing end of the trocar, comes the drain tubing. After cutting the trocar from the drain tubing, the surgeon or assistant must replace the protective cover onto the sharp point.

The EuTrochar is different from the predicate drain installation trocars in that the protective cover "Sheath" is not removed by the surgeons' hand. The protected EuTrochar, (Sheath covering the sharp point) is inserted into a handle, ("Deployer") into which it is automatically securely fastened. Grasping the Deployer by the handles, the surgeon opens it, releasing the EuTrochar from the protective Sheath. The Sheath remains in the head (Receiver) of the Deployer and acts as a target for the sharp point when later the Deployer is closed, returning the sharp point on the EuTrochar into the Sheath. With the Deployer opened, there is ample clearance tissue to fit between the sharp point of the EuTrochar and the Receiver target. Holding the Deployer by the handles, the surgeon and associates are clear of the sharp point as it is placed at the desired spot for the drain inside the soft tissue flap. The Deployer is positioned such that the target is placed at the desired exit position of the drain tubing. Squeezing the handles closes the Deployer and therefore advances the EuTrochar through the soft tissue and back into the Sheath. Since the target supports the tissue, the EuTrochar is advanced through the soft tissue, without fingers or hands near the

sharp point. And, the drain tube will be in the exact position desired by the surgeon. The EuTrochar is automatically locked into the Sheath when the Deployer is closed. The tubing end of the EuTrochar is released from the Deployer and the Deployer is used to pull the drain tubing through the soft tissue. No fingers come close to the point, as it is enclosed with the Sheath. When the tubing has been pulled far enough, the EuTrochar, protected by the Sheath, is easily released from the Receiver. It is cut from the tubing and discarded into the hazardous waste depository.

Thus, the differences between predicate drain installation trocars and the EuTrochar are in the protective cover over the sharp point and in the handle (Deployer) which replaces the need for pliers and keeps fingers clear of the sharp point.

This product has no Performance Standards. Technicians in Special Devices performed exhaustive tests with prototype hardware using both plastic tissue and animal tissue. Many drain installations were performed on dead animal tissue. Additionally, as an aid to writing the Technique Manual and to ascertain that the hardware could be used successfully by outside surgeons and support personnel, Special Devices developed a Trials Protocol, which we consider a "bench trial." Employing plastic sheet as ersatz tissue, a series of EuTrochars and several Deployers were used in trials. No failures were experienced.

The conclusions of each tester were that there had been no failure and that the devices did not present a hazard to a prospective patient nor to surgical personnel.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 18 2005

Mr. Joseph John Spranza, III
President
Special Devices Incorporated
12493 Old Rough and Ready Highway
Grass Valley, California 95945

Re: K050957
Trade/Device Name: EuTrochar
Regulation Number: 21 CFR 878.4800
Regulation Name: Manual surgical instrument for general use
Regulatory Class: I
Product Code: MDM
Dated: March 21, 2005
Received: April 15, 2005

Dear Mr. Spranza:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K050957

Indications for Use

510(K) Number (if known): K050957

Device Name: EuTrochar

Indications For Use: FOR USE IN INSTALLING SURGICAL DRAINS

Prescription Use: By Surgeon
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use _______
(Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Devices Evaluation (ODE)

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