



510(k) Summary

K971334

June 11, 1997

1. Submitter Name, Address, and Date of Submission:

Miss Karenann J. Brozowski
Group Regulatory Affairs Director
Pilling Weck Group
Tall Pines Park
Jaffrey, NH 03452

Telephone: (603)532-7706

Contact: Same as above.

2. Names of the Device, Common, Proprietary(if Known), and Classification.

Classification Name: Secondary Trocar with Sleeve

Common Name: Secondary Trocar with Sleeve

Proprietary Name: Pilling Weck Secondary Flexible Sleeve and Trocar

3. Identification of the legally marketed device to which the submitter claims equivalence.

The Pilling Weck Trocar and Sleeve is substantially equivalent to the Core Dynamics Entree II, Apple Medical Hunt Reich Secondary Trocar, and the Access Surgical Access Single Use Trocar and Sleeve.

4. Description of the Device:

The device consists of Trocar and Sleeves, with integral and separately available Single Use Disposable Caps. The Sterile Disposable Cap Assembly consists of a universal adapter seal, which is used as a port of entry for the instrument/probe and used to minimize leakage and loss of pneumoperitoneum.

The Optional Disposable Cap Assembly is packed sterile in individual pouches or two to a pouch.

The Trocar, sizes 3mm.-15mm., is constructed with a polymer hub and shaft with stainless steel tip and is available in pyramidal style.

A Teleflex Company

One Weck Drive, P.O. Box 12600
Research Triangle Park, North Carolina 27709
(919) 544-8000

The Sleeve, proportionally sized, is made of polymer and comes with or accepts the Disposable Cap Assembly to seal the port of entry for the surgical instrument.

5. Intended Use of the Device:

The Trocar and Sleeve are manual surgical instruments used to support a cut down(lap approach) on secondary puncture placement. The trocar is used in Endoscopic Surgery(Gynecologic, general and other laparoscopic procedures and Thoracic) for incision and peritoneal access for positioning of the hollow sleeve.

Once the trocar is removed, the port of entry provided by the sleeve, through the cap, is used with manual surgical instruments, endoscopic instruments, laproscopes, and probes. There is an seal on the cap, which closes the port of entry.

The usage of this product is identical to previous devices, which have the same technological characteristics.

6. Summary of Technological Characteristics:

The following technological characteristics are the same or equivalent as predicate devices:

The Trocar, consisting of a polymer shaft and hub with stainless steel tip, is equivalent to the predicates.

The sleeve used with the Trocar is treaded, which is equivalent to the predicates.

The Cap Assembly contains the seal, which is used to minimize the leakage from the pneumoperitoneum, which is equivalent to the predicates.

summm/o



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 1997

Ms. Karenann J. Brozowski
Group Regulatory Affairs Director
Pilling Weck Group
Tall Pines Park
Jaffrey, New Hampshire 03452

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Re: K971334
Trade Name: Pilling Weck Secondary Flexible Sleeve with Trocar
Regulatory Class: II
Product Code: GCJ
Dated: April 4, 1997
Received: April 10, 1997

Dear Ms. Brozowski:

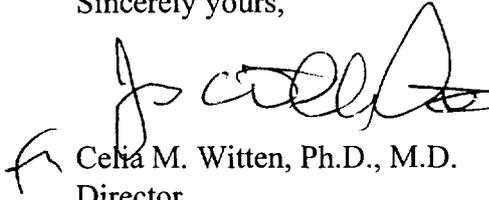
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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". The signature is stylized and written over the printed name.

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

510(k) Number (if known): K971334

Device Name: Pilling Weck Secondary Flexible Sleeve with Trocar

Indications For Use:

The Pilling Weck Secondary Flexible Sleeve with Cap and Trocar are manual surgical instruments used to support a cut down (lap approach) on secondary puncture placement.

The Trocar is used in Endoscopic Surgery (Gynecologic, general and other laparoscopic procedures and thoracic) for incision and peritoneal access for positioning of the hollow flexible sleeve.

Once the Trocar is removed, the port of entry provided by the sleeve through the cap, is used with manual instruments, laproscopes, and probes.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K971334

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)