K982797

NOV 30 1998

510(k) Summary

August 7, 1998

General Information:

Applicant: Luther Medical Products, Inc.
14332 Chambers Road
Tustin, CA 92780-6912
Phone: (714) 544-3002
Fax: (714) 544-7273

Contact: Kathleen Roberts
(714) 544-3002, ext. 216

Common Name: Catheter Introducer
Trade Name: Blunt T-Peel Plastic Sheath Introducer
Classification Name: Catheter Introducer

Predicate Devices

Luther Medical Products, Inc.
T-Peel Introducer
K924562

Bio-Plexus, Inc.
Punctur-Guard® Blood Collection Needle
K895024

Device Description

An over-the-needle peel-away plastic sheath catheter introducer which includes a blunting feature to blunt the tip of the needle after venous access.

Intended Use

Used to facilitate placement of an intravascular catheter through the skin into a vein and when used according to the Directions For Use, may reduce the risk of an accidental needlestick.

Comparison to Predicate Devices

Substantially equivalent to the T-Peel introducer with the addition of a needlestick protection feature that is comparable in safety and effectiveness to a similar feature in the Punctur-Guard® Blood Collection Needle.

Tests

The T-Peel Plastic Sheath Introducer has been on the market for several years and was previously tested and qualified. There are no design, dimensional or material changes to the device. Therefore no testing of the catheter introduction features are necessary.

The additional needlestick protection feature of the Blunt T-Peel Plastic Sheath Catheter Introducer has been evaluated according to a documented test protocol. All test results were satisfactory and met the protocol's requirements. The activation force was within specified limits. The puncture force with the shielded needle exceeded that with the unshielded needle in all cases. The force to override the needle shielding feature exceeds the minimum requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NOV 30 1998

Ms. Kathleen Roberts
Regulatory Affairs Manager
Luther Medical Products, Inc.
14332 Chambers Road
Tustin, CA 92780-6912

Re: K982797
Trade Name: Blunt T-Peel Plastic Sheath Introducer
Regulatory Class: II
Product Code: DYB
Dated: October 22, 1998
Received: October 23, 1998

Dear Ms. Roberts:

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 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). 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) 594-4586. 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" (21CFR 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/dsma/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K982797

Device Name:

Blunt T-Peel Plastic Sheath Introducer

Indications For Use:

The Blunt T-Peel Plastic Sheath Introducer is used to facilitate placement of a peripherally inserted intravenous catheter through the skin into a vein and when used according to the Directions For Use, may reduce the risk of an accidental needlestick.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K982797

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)