JUL 9 1998

K 981527

510(k) SUMMARY

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

The assigned 510(k) number is:

Submitted by: Donna A. Crawford
Manager, Corporate Regulatory Affairs
Mentor Corporation
5425 Hollister Ave.
Santa Barbara, CA 93111

Telephone: (805) 681-6000 extension 304
FAX: (805) 681-6004

Date Prepared: April 24, 1998

Device Name

Proprietary Name: Mentor Pathway™ Introducer/Dilator

Common Name: Introducer/Dilator

Substantial Equivalence Claim

The Mentor Pathway Introducer/Dilator is similar to devices used to dilate the skin and provide an access port for surgical procedures. Examples of equivalent devices include the Ethicon Non-shielded Surgical Trocar (K963760), the Ximed surgical trocars and cannulae (K933458) and the Applied Medical Technology Endoscopic Access Device (K960232). The Mentor Pathway Introducer/Dilator is also similar in design and intended use to the Lysonix Lipoplasty Access Port (K980763).

Indications For Use

The Mentor Pathway Introducer is indicated for use as an operating port at the skin insertion site when instruments are utilized beneath the dermal layer for lipoplasty surgery applications. The Dilator is indicated for dilating the dermal layer and aiding in the insertion of the Pathway Introducer. The Plug is indicated for sealing the lumen of the Pathway Introducer when not in use.

Device Description

The Mentor Pathway Introducer/Dilator system consists of three (3) primary components: Introducer, Dilator and Plug.

The Dilator consists of a dilating stem and a handle. It is used to facilitate the insertion of the Introducer.

The Pathway Introducer consists of a threaded distal end which is threaded into the skin at the insertion site, and a conical section which remains outside the skin. There is a longitudinal hole in the Introducer through which a cannula and sheath (or other similar surgical instrumentation) are inserted, and there is a seal inside the hole which wipes excess liquid from the cannula and sheath during withdrawal. The Introducer acts as an access port during the insertion of cannulae and other operating instruments to a desired surgical site beneath the dermal layer.

The Plug is used to seal the lumen of the Pathway Introducer when not in use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 9 1998

Ms. Donna A. Crawford
Manager, Corporate Regulatory Affairs
Mentor Corporation
5425 Hollister Avenue
Santa Barbara, California 93111

Re: K981527
Trade Name: Mentor Pathway Introducer/Dilator
Regulatory Class: II
Product Code: MUU
Dated: April 24, 1998
Received: April 28, 1998

Dear Ms. Crawford:

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 requirement, 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,

for 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): K981527

Device Name: MENTOR Pathway™ Introducer/Dilator

Indications For Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981527

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

(Optional Format 1-2-96)