MAY 20 1998 K981188

10. SMDA Summary of Safety and Effectiveness - "510(k) Summary"

A. Submittor Information

Microline, Inc.
100 cummings Center
Suite 350-G
Beverly, MA 01915

Telephone: (508) 922-9810
Contact Person: Mr. Huges de Laforcade
President

Date Prepared: March 31, 1998

B. Device Identification

Common/Usual Name: Electrosurgical Cautery Probes
Proprietary Name: Not Yet Determined

C. Identification of Predicate Device(s)

The Microline Electrosurgical Cautery Probes are substantially equivalent to those offered by Olsen Electrosurgical Inc. (K913108) previously cleared and currently marketed.

D. Device Description

The Microline Electrosurgical Cautery Probes are a line of non-sterile, reusable 3 mm and 5 mm diameter instruments used to deliver energy from an independent monopolar electrosurgical generator to cauterize tissue during laparoscopic (inclusive of endoscopic) surgical procedures where instruments are introduced into the body through a cannula.

E. Substantial Equivalence

The Microline Electrosurgical Cautery Probes are substantially equivalent to the Olsen Electrosurgical reusable lapasocopic electrodes (K913108). Differences that exist between these devices relating to technical specifications, materials, and physical appearance do not affect the relative safety or effectiveness of the Microline Electrosurgical Cautery Probes relative to its predicate.

The Microline Electrosurgical Cautery Probes are intended to delivery energy from an independent monopolar electrosurgical generator to cauterize tissue during laparoscopic (inclusive of endoscopic) surgical procedures where instruments are introduced into the body through a cannula.

11. Premarket Notification: Truthful and Accurate Statement

Premarket Notification

Truthful and Accurate Statement
(As required by 21 CFR 807.87(j))

I certify that, in my capacity as President of Microline, Inc., I believe to the best of my knowledge, that all data and information submitted in the Premarket Notification are truthful and accurate, and that no material fact has been omitted.

H de Laforcade

Signature

Hughes de Laforcade

MARCH 31, 1998

Date

K981188

Premarket Notification Number

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 20 1998

Microline, Incorporated
C/O Ms. Jacqueline E. Masse
Senior Consultant
Interactive Consulting
70 Walnut Street
Wellesley, Massachusetts 02181

Re: K981188
Trade Name: Microline Electrosurgical Cautery Probes
Regulatory Class: II
Product Code: GEI
Dated: March 31, 1998
Received: April 2, 1998

Dear Ms. Masse:

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,

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): K981188

Device Name: **Electrosurgical Cautery Probes**

Indications For Use:

The Microline reusable 3 mm and 5 mm diameter Electrosurgical Cautery Probes are intended to deliver energy from an independent monopolar electrosurgical generator to cauterize tissues during laparoscopic (inclusive of endoscopic) surgical procedures where instruments are introduced into the body through a cannula.

(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 K981188

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

(Optional Format 1-2-96)