

MAR 27 1998

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

K980758

A. Submitter Information

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

Telephone: (978) 922-9810

Contact Person: Mr. Hugues de Laforcade
President

Date Prepared: February 25, 1998

B. Device Identification

Common/Usual Name: Manual Detachable Surgical Instruments,
Proprietary Name: "3 MM Selec-Tip" Laparoscopic Instruments

C. Identification of Predicate Device(s)

The "3 MM Selec-Tip" Laparoscopic Instruments are substantially equivalent to their predicate, "Selecta-Tip (K970826) and Richard Wolf Medical Instruments (K973648), previously cleared and currently marketed.

D. Device Description

The "3 MM Selec-Tip" Laparoscopic Surgical Instruments are a line of non-sterile, reusable small diameter instruments used to cut and dissect various abdominal tissue for use in endoscopic, including laparoscopic, surgical procedures. The device can be used with monopolar electrosurgical generators.

E. Substantial Equivalence

The Microline "3 MM Selec-Tip" Laparoscopic Scissors Instruments are substantially equivalent to the Microline "Selecta-Tip (K970826) and Richard Wolf Medical Instruments (K973648). Differences that exist between these devices relating to technical specifications, materials, and physical appearance do not affect the relative safety or effectiveness of the "3 MM Selec-Tip" relative to its predicates.

"3 MM Selec-Tip" Laparoscopic scissors tips are intended for use to cut and dissect various abdominal tissue in endoscopic, including laparoscopic surgical procedures where small diameter instruments are introduced into the body through a cannula.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 27 1998

Ms. Jacqueline E. Masse
Sr. Consultant
Microline, Incorporated
c/o Interactive Consulting Incorporated
70 Walnut Street
Wellesley, Massachusetts 02181

Re: K980758
Trade Name: 3MM Selec-Tip Laparoscopic Scissors
Regulatory Class: II
Product Code: GEI
Dated: February 25, 1998
Received: February 27, 1998

Dear Ms. Masse:

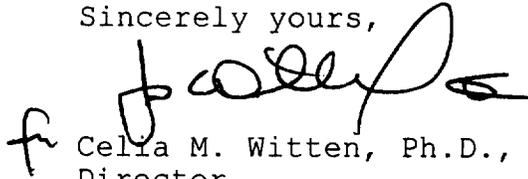
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (Pre-market 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 pre-market 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 'C. Witten', is written over the typed name. To the left of the signature is a small, stylized handwritten mark that looks like a lowercase 'f'.

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): _____

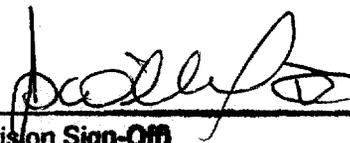
Device Name: "3 MM Selec-Tip" Laparoscopic Scissors

Indications For Use:

- **Cutting and Dissecting Various Abdominal Tissue during Endoscopic (inclusive of laparoscopic) Surgical Procedures.**

(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

K980788

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)