OCT 21 1998

K 982984

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: (978) 922-9810
Contact Person: Mr. Huges de Laforcade
President

Date Prepared: August 24, 1998

B. Device Identification

Common/Usual Name: Manual Detachable Surgical Instruments
Proprietary Name: ACCUSHEAR Laparoscopic Surgical Instruments

C. Identification of Predicate Device(s)

The Microline ACCUSHEAR Laparoscopic Surgical Scissors Instruments are substantially equivalent to their predicates offered by Microline Inc. "Re-New" (K962119) and "Selec-Tip" (K980758) previously cleared and currently marketed.

D. Device Description

The Microline ACCUSHEAR Laparoscopic Surgical Instruments are a line of non-sterile, reusable 5 mm diameter instruments used to cut and dissect various abdominal tissue for use in endoscopic, including laparoscopic surgical procedures where instruments are introduced into the body through a cannula. The device is used with monopolar electrosurgical generators.

E. Substantial Equivalence

The Microline ACCUSHEAR Laparoscopic Surgical Scissors Instruments are a modified version of the predicate Microline "Re-New" (K962119) with a minor device modification related to the shaft and handpiece connection and does not affect the relative safety or effectiveness of the Microline ACCUSHEAR Laparoscopic Surgical Scissors Instruments relative to their predicate.

The Microline ACCUSHEAR Laparoscopic Surgical Instruments are intended to delivery energy from an independent monopolar electrosurgical generator to cut and dissect various abdominal tissue for use during laparoscopic, inclusive of endoscopic surgical procedures where instruments are introduced into the body through a cannula.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 21 1998

Microline, Inc.
Ms. Jacqueline E. Masse
Senior Consultant
c/o Interactive Consulting, Inc.
70 Walnut Street
Wellesley, Massachusetts 02481

Re: K982984
Trade Name: ACCUSHEAR Laparoscopic Surgical Instruments
Regulatory Class: II
Product Code: GEI
Dated: August 24, 1998
Received: August 26, 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,

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): K982984

Device Name: **ACCUSHEAR Laparoscopic Surgical Scissors Instruments**

Indications For Use:

**Cutting and Dissecting Various Abdominal Tissue during Endoscopic (inclusive of laparoscopic) 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)

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982984