

K 974066

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

JAN 22 1998

A. Submitter Information

Microline, Inc.  
181 Elliott Street  
Suite 915  
Beverly, MA 01915

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

Date Prepared: October 24, 1997

B. Device Identification

Common/Usual Name: Manual Detachable Surgical Instruments  
Proprietary Name: "Re-New Forceps" Laparoscopic Surgical Tips

C. Identification of Predicate Device(s)

The "Re-New Forceps" Laparoscopic Surgical Tips are substantially equivalent to their predicate, "Re-New" (K962119), previously cleared and currently marketed.

D. Device Description

The "Re-New Forceps" Laparoscopic Surgical Tips are an extension of the "Re-New" Laparoscopic Instruments product line used to cut, grasp, and dissect various abdominal tissue during Endoscopic (inclusive of laparoscopic) surgical procedures.

The "Re-New Forceps" Laparoscopic Surgical Tips consist of a series reusable tip configurations. The tip assembly, designed with a double thread, permits simple and reliable attachment and detachment of the desired tip to the shaft of the handle/shaft component. Tip configurations include:

- Grasper,
- Fenestreded Forceps,
- "Dolphin Nose" Dissector,
- "Babcock", and
- "Maryland" Dissector

E. Substantial Equivalence

The technical characteristics of the "Re-New Forceps" Laparoscopic Surgical Tips are almost identical to those of the Microline "Re-New" (K962119). Differences that exist between these devices relating to technical specifications, materials, and physical appearance do not affect the relative safety or effectiveness of the "Re-New Forceps" relative to its predicate.

The "Re-New Forceps" Laparoscopic Surgical Tips are intended for use to cut, grasp, and dissect various abdominal tissue in endoscopic, including laparoscopic surgical procedures where instruments are introduced into the body through a cannula.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 22 1998

Mr. Hughes de Laforcade  
President  
Microline, Incorporated  
181 Elliott Street, Suite 915  
Beverly, Massachusetts 01915

Re: K974066  
Trade Name: "RE-NEW FORCEPS" Laparoscopic Surgical Tips  
Regulatory Class: II  
Product Code: GEI  
Dated: October 24, 1997  
Received: October 27, 1997

Dear Mr. de Laforcade:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are 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 devices, 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.

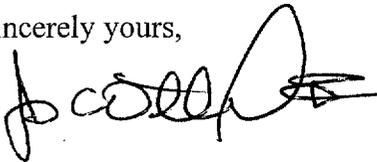
If your devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification submissions 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.

Page 2 - Mr. de Laforcade

This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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,



*fr* 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

The generator manufacturers which are compatible with the "Re-New Forceps"  
Laparoscopic Surgical Tips are as follows:

1. Bovie
2. Valley Lab, Inc.
3. CIRCOM ACMI
4. Elmed, inc.
5. Leisegang Medical

#### 6.5 Intended Use

The "Re-New Forceps" Laparoscopic Surgical Tips are intended to cut, grasp, and dissect various abdominal issue for use in endoscopic, including laparoscopic surgical procedures where instruments are introduced into the body through a cannula.

**CAUTION: Federal Law (USA)  
restricts this device to use or sales  
by or on order of a physician.**

#### 7. Packaging

The "Re-New Forceps" stainless steel reusable laparoscopic surgical tips are packaged non-sterile in a plastic blister with 5 blisters in a carton. A copy of the labeling for this carton is located in Appendix A.