3/15/99
K983882

# SUMMARY OF SAFETY AND EFFECTIVENESS
# MICRO MEDICAL DEVICES, INC. MICRO ENDOSCOPE

**The Summary of Safety and Effectiveness on Micro Endoscope reflects data available and presented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies may require alterations of the conclusions or recommendations set forth.**

## Intended Use

Micro Arthroscope is intended for insertion into a small incision or puncture (through a cannula) to view the surgical site of small and large joints in conjunction with cameras.

## Caution

Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

## Contraindication

Bending or prying with scope will damage optics.

## Precautions

- Surgical laser and mechanical cutting instruments can damage the scope.
- Do not allow the arthroscope tip to come into contact with hard or sharp objects.
- Use this device only with a xenon light source (maximum 300 watts) and Micro Medical Devices, Inc camera.

## Substantial Equivalency Information

The Micro Arthroscope is similar to the Galileo Arthroscope currently offered by Galileo Electro-Optics Corporation.

| | Galileo | Micro Medical |
|---|---|---|
| Materials | Stainless Steel | Stainless Steel<br>Polyimide |
| Sterilization | Reusable: EO and Steris | Single Use: EO<br>SAL $10^{-6}$ |

The intended use and technological characteristics of these devices do not vary significantly. The safety and effectiveness of the Micro Medical Endoscope is comparable to that of the Galileo Electro-Optics Corporation Arthroscope

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 15 1999

Mr. Jim Ohneck
General Manger
Micro Medical Devices, Inc.
11000 Cedar Avenue
Suite 445
Cleveland, Ohio 44106

Re: K983882
Trade Name: Micro Endoscope
Regulatory Class: II
Product Code: HXR
Dated: February 3, 1999
Received: February 5, 1999

Dear Mr. Ohneck:

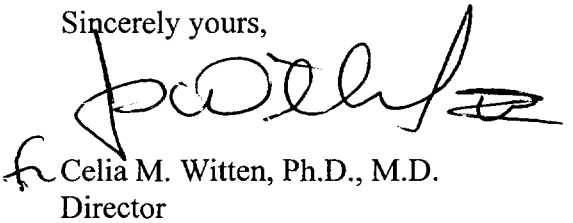
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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): 983882

Device Name: Micro Endoscope

Indications For Use:

Micro Endoscope is intended for insertion into a small incision or puncture (through a cannula) to view the surgical site of small and large joints of the wrists, ankles, elbows, knees, or shoulders in conjunction with cameras.

**CAUTION:** Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

**CONTRAINDICATIONS:** Bending or prying with scope will damage optics.

(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 K983882

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

(Optional Format 1-2-96)