

mdi

K 970937

Sept. 26, 1997

Exhibit #1
510(k) Summary
Page 1 of 2

510(K) Summary
MIST Interchangeable Scope System™

Submitter Information:

Robert Heffer
Director of Operations
Minimally Invasive Surgical Technologies (MIST)
3310 US 70 West
Smithfield, NC 27577
Telephone Number: (919) 989-6478

510(k) Summary Prepared By:

Carolann Kotula
MDI Consultants, Inc.
55 Northern Boulevard
Great Neck, NY 11021
Telephone Number: (516) 482-9001

Date 510(k) Summary Prepared: March , 1997

Name of the Device:

Trade or Proprietary Name: MIST Micro Interchangeable Scope Systems™, various catalog numbers.

Common Name: Rigid Laparoscope

Classification Name: Laparoscope, General and Plastic Surgery, Endoscope and Accessories, including instruments (21 CFR Part 876.1500)



Identification of Legally Marketed Device to which the Submitter Claims Equivalence:

The MIST electrosurgical is identical in intended use and materials to the Galileo Endoscope marketed by Galileo Electro-Optics Corporation under K962116.

Description of the Subject Devices:

The MIST Micro Interchangeable Scope System™ is a two piece, rigid, fiber-optic laparoscope. The universal eyepiece (MicroView Handle)) may be used with several variable sizes of shafts. No working channel is provided.

The devices are re-usable, and will be sold non-sterile with instruction for cleaning, sterilization, and re-use.

Intended Use of the Subject Devices

The MIST Micro Interchangeable Scope System™ is intended to be used by trained physicians for the illumination and direct visualization of body cavities, hollow organs and canals during diagnostic and general surgical procedures.

Technological Characteristics of the Subject Devices

There are no significant technological characteristic of the MIST electrosurgical probes and the predicate devices. The MIST devices are identical to the predicate except that it is a two piece device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

MIST
c/o Ms. Carolann Kotula
Official Correspondent
MDI Consultants, Inc.
55 Northern Boulevard
Great Neck, New York 11021

SEP 26 1997

Re: K970937
Trade Name: Mist Micro Interchangeable Scope System™
Regulatory Class: II
Product Code: GCJ
Dated: July 1, 1997
Received: July 3, 1997

Dear Ms. Kotula:

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.

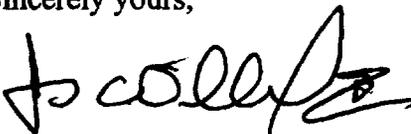
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice 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. 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,


fm 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

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510(k) Number (if known): K970937

Device Name: MIST Micro Interchangeable Scope System™

Indications For Use:

The MIST Micro Interchangeable Scope Systems are rigid, two piece fiber-optic endoscopes intended for the illumination and direct visualization of body cavities, hollow organs and canals during general diagnostic procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDREH, Office of Device Evaluation (ODE)

[Handwritten Signature]

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K970937

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)