K983527

JAN 19 1999

DOFI COMMUNICATIONS provides the following 510(k) Summary:

We have taken the terminology from the Reference Manual-"Pre-market Notification 510(k): Regulatory Requirements for Medical Devices" (FDA 92-4158).

Summary

DOFI Communications confirms that the Miniature Endo/Laparoscope listed in this 510(k) is IDENTICAL in every way to the device marketed by Solos Endoscopy under **K983538** and therefore this device is **Substantially Equivalent**, in terms of physical characteristics, to the legally marketed devices already in commercial distribution. These other devices are made/marketed by Solos Endoscopy, Inc., Mitsubishi Inc. America, and no less than 20 other companies with similar devices with very similar characteristics. These other devices now under commercial distribution are: K936857, and K935834. Others with very similar characteristics are listed and under commercial distribution by Omega under K91109C and Candela Laser under K910732. Other manufacturer's, such as, but not limited to; Fujinon, Olympus, Baxter, Stryker, Linvatec, Karl Storz et al, market similar devices and are cited in this document as having similar and very comparable products

The design of SOLOS ENDOSCOPY made/marketed endoscope K983538 is identical in every way as the scope approved for intended uses that are listed in this document. The assessment of this device, from DOFI COMMUNICATIONS', point of view is as follows: The physical characteristics, except for miniaturization, are identical as the approved device and this predicate device has been accepted with respect to: performance specifications, composition, intended use, technology employed, bio-compatibility, manufacturing, QC, physical testing, etc. These above minor changes have no impact on the safe use and/or effectiveness of the device.

For information purposes and completeness DOFI COMMUNICATIONS has also cited the other legally marketed devices ie: (Olympus, Pentax, etc.), in this filing to illustrate the wide, general use of many other similar devices. This wide use has led to the safe use of the device in many practitioner's hands for the same intended use-'***Use for visualization inside the human body to view surgical procedure(s), by physician.***'

DOFI COMMUNICATIONS, therefore, contends there is Substantial Equivalence of the device and the device's Intended Uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 19 1999

Mr. Tony Anthony
President and Chief Executive Officer
DOFI Communications, Inc.
150 West 51st Street, Suite 1108
New York, New York 10019

Re: K983527
Trade Name: Miniature Endo/Laparoscope
Regulatory Class: II
Product Code: GCJ
Dated: December 22, 1998
Received: January 11, 1999

Dear Mr. Anthony:

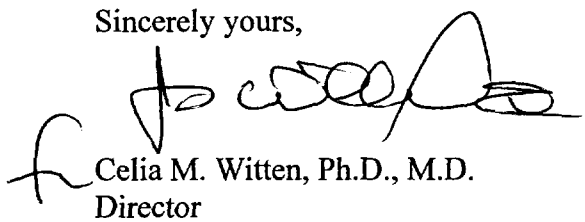
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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



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) #: K983527

Device Name: Miniature Endo/Laparoscope

Indications for Use:

The Indications for this device use is for medical practitioner needing visualization of soft tissue, either through a natural orifice or incision.

Intended Use:

'Use for visualization inside the human body to view surgical procedure(s), by physician.'

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983527