NOV 6 1998

Exhibit 8 Summary

K983538

Summary

SOLOS ENDOSCOPY feels the **Minature endo/Laparoscope** listed in this Special 510(k) is **Substantially Equivalent**, in terms of physical characteristics, to the legally marketed devices already in commercial distribution. These devices are made or specified by, and /marketed by Solos Endoscopy, Inc., and no less than 20 other companies with similar devices with very similar characteristics. These devices now under commercial distribution are K932987, K931065 and K926166. Others with very similar characteristics are listed and under commercial distribution by Omega,, Candela Laser and other manufacturer's, such as, but not limited to; Fujinon, Olympus, Baxter, Stryker, Linvatec, Karl Storz et al. Each markets similar devices.

The design of SOLOS ENDOSCOPY made/marketed endoscopes K971996, K926166 is virtually the same as scopes approved for intended use for the purpose of visualization of surgical procedures. Each 510(k) intended use is tabulated in this document.

The assessment of this device, from, SOLOS ENDOSCOPY'S point of view is as follows: The physical characteristics, except for miniaturization, are virtually the same as approved devices. The intended use of visualization of surgical procedure is virtually identical and each has been accepted with respect to: performance specifications, composition, 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 6 1998

Mr. Paul Dias
Quality Assurance Manager
Solos Endoscopy, Inc.
41 Brooks Drive
Braintree, Massachusetts 02184

Re: K983538
Trade Name: Miniature Endo/Laparoscope
Regulatory Class: II
Product Code: GCJ
Dated: October 07, 1998
Received: October 09, 1998

Dear Mr. Dias:

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

Intended use statement for DF-0012 K983538

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

Indications for Use:

The Indications for this device use is when medical practitioner needs visualization in order to view surgical procedures, gaining access either through a natural orifice or incision.

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983538