

NOV 21 1997

K973232

**510 (k) SUMMARY
OLYMPUS SEPS SYSTEM**

SUBFASCIAL ENDOSCOPIC PERFORATING VEIN SURGERY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR, Section 807.92.

Device Name: Olympus SEPS System

Common/Usual Name: Subfascial Endoscopic Perforating Vein Surgery System

Classification Name: Class II, 21 CFR 876.1500
Endoscope and Accessories.

Predicate Devices: Olympus Subcutaneous Endoscopy System (K963184)
Endoscopic Plastic/Reconstructive and Aesthetic Surgery Endoscopes (K950076)
Endoscopic Plastic/Reconstructive and Aesthetic Surgery Hand Instruments (K950103)
Olympus Ultrathin Ureteroscope (K951855)
Olympus Nasal & Sinus Endoscopes (K944072)
KSEA Instrument Set for Endoscopic Surgery of Superficial Veins and Fascia of the lower Extremities (K960903)
Richard Wolf Instruments for Endoscopic Subfascial Discision of Perforating Veins - ESDP (K964258)

**Prepared & Submitted By:
(Contact Person)** Mr. Subhash Patel
Olympus America Inc.
Endoscope Division
Two Corporate Center Drive
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(516) 844-5481

**Summary Preparation
Date:** 08/27/97

Statement of Intended Use:

The Olympus SEPS System is designed for subcutaneous endoscopy -- more specifically, for endoscopically gaining access to vessels (arteries veins, ducts, nerves) in subcutaneous and subfascial surgical planes in the lower extremities for endoscopic observation, diagnosis, and treatment.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Subhash R. Patel
Regulatory Affairs Associate
Olympus America, Inc. Endoscope Division
Two Corporate Center Drive
Melville, New York 11747-3157

Re: K973232
Trade Name: Olympus Subfascial Endoscopic Perforating Vein Surgery (SEPS)
System, its associated accessories and ancillary equipment
Regulatory Class: II
Product Code: GCJ
Dated: August 27, 1997
Received: August 28, 1997

Dear Mr. Patel:

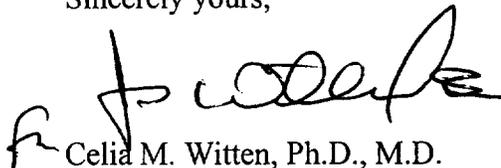
We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date 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 (Pre-market 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. Failure to comply with the GMP regulation may result in regulatory action. 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.

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,



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

