

MAY 28 1997

K970797

**510 (k) SUMMARY
OLYMPUS PSD-20 ELECTROSURGICAL SYSTEM**

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 PSD-20 Electrosurgical System and its associated accessories.

Common/Usual Name: Electrosurgical Units

Classification Name: 21 CFR 878.440, Class II
Electrosurgical Cutting and Coagulation Device and Accessories.

21 CFR 876.4300, Class II
Endoscopic Electrosurgical Unit and Accessories.

Predicate Devices: Olympus PSD-10 Electrosurgical Unit (K911904)

Prepared & Submitted By: Mr. Subhash Patel
(Contact Person) Olympus America Inc.
Endoscope Division
Two Corporate Center Drive
Melville, New York 11747-3157
(516) 844-5481

Summary Preparation

Date: 02/24/97

Statement of Intended Use:

PSD-20 Electrosurgical Unit

The Olympus PSD-20 has been designed for use in medical facilities under the supervision of a trained physician. It has been designed for general and endoscopic electrosurgery (cutting and coagulation) in conjunction with Olympus designated electrosurgical accessories, endoscopes (fiberscopes and videoscopes) applicable for electrosurgery, light sources and ancillary equipment. Do not use the instrument for any purpose other than its intended use.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 1997

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

Re: K970797
Trade Name: Olympus PSD-20 Electrosurgical System and its associated accessories
Regulatory Class: II
Product Code: GEI
Dated: February 27, 1997
Received: March 4, 1997

Dear Mr. Patel:

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.

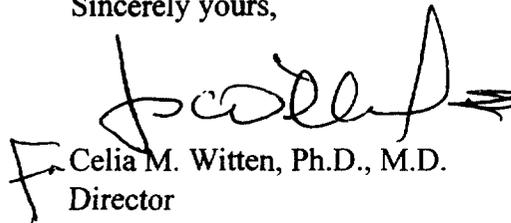
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

Page 2 - Mr. Subhash R. Patel

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,

A handwritten signature in black ink, appearing to read 'C. Witten', with a stylized flourish at the end.

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

Indications for Use Statement
(Revised: May 16, 1997)

510(k) Number (if known): K970797

Device Name: Olympus PSD-20 Electrosurgical System and its associated accessories.

Indications for Use:

The Olympus PSD-20 has been intended to cut and coagulate tissues within the gastrointestinal (GI) tract. The PSD-20 is designed to be used in conjunction with the electrosurgical accessories and the designated Olympus endoscopes that are applicable for electrosurgery.

The Olympus PSD-20 has been designed for use in medical facilities under the supervision of a trained physician. It has been designed for general and endoscopic electrosurgery (cutting and coagulation) in conjunction with Olympus designated electrosurgical accessories, endoscopes (fiberscopes, videoscopes, and rigid scopes) applicable to electrosurgery, light sources and ancillary equipment. Do not use the instrument for any purpose other than its intended use.

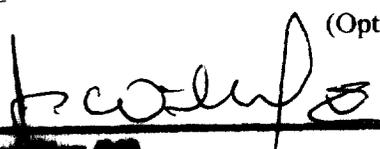
(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(per 21CFR 801.109)

OR

Over-the Counter Use _____
(Optional Format 1-2-96)



(Division of General Restorative Devices)
Division of General Restorative Devices
510(k) Number _____

K970797