K 982289

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510(k) SUMMARY
OLYMPUS HEAT PROBE UNIT HPU-20

A. Submitter's Name, Address, Phone and Fax Numbers

1. Manufacturer of the subject devices

Name & Address of manufacturer:	Olympus Optical Co., Ltd. 22-2 Nishi-Shinjuku, 1-Chome, Shinjuku-ku, Tokyo 163-8610 Japan
Registration No.:	8010047
Address, Phone and Fax Numbers: of R&D Department, Endoscope Division	2951 Ishikawa-Cho, Hachioji-shi, Tokyo 192-8507 Japan TEL 0426-42-5101 FAX 0426-46-2786

B. Name of Contact Person

Name: Address, Phone and Fax Numbers:	Ms. Laura Storms-Tyler Olympus America Inc. Endoscope Division Two Corporate Center Drive Melville, New York 11747-3157 TEL: (516) 844-5688 FAX: (516) 844-5416

C. Device Name, Common Name, Classification Name and Predicate Devices

Device Name:	Heat Probe Unit HPU-20 Water Container for model HPU-20 MAJ-526 Water Pump for model HPU-20 MAJ-527 Foot Switch for model HPU-20 MAJ-528 Heat Probe CD-110##/120##
Common Name:	Heat Probe Unit
Classification Name:	No Classified name
Predicate Device:	HPU Heat Probe Olympus K851096

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D. Description of the Device

The Heat Probe Unit HPU-20 and its associated accessories have been designed for thermal cautery. The Heat Probe Unit HPU-20 and its accessories consist of the heat probe unit, water container, water pump, foot switch and heat probe. Bleeding sites are thermo-cauterized by the heat that is conveyed via a non-stick coating from the tip of the heat probe to the tissue surface.

The system is easy to use, poses no electrical hazard to the patient or physician, and is extremely effective as a means of nonsurgically treating severe bleeding in the gastrointestinal tract. The probes are available in two diameters (3.4 mm and 2.7 mm) and are designed to be used through the biopsy channel of any standard flexible endoscope. The system will deliver a selected amount of thermal energy, from five through thirty joules, directly to the bleeding site.

E. Intended Use of the Device(s)

The Heat Probe Unit HPU-20 has been designed for thermal cautery with Olympus Heat Probes.

The Heat Probe has been specifically designed to thermo-cauterize bleeding in the gastrointestinal tract under endoscopic observation.

F. Summary of the Technological Characteristics of the Device Compared to the Predicate Device(s)

1. Water Pump

   The Water Pump of the subject device is a detachable roller pump, which can be autoclaved.

2. Heat Probe

   The heater element installed inside the distal end of the Heat Probe of subject devices is a positive temperature coefficient resistor which can be autoclaved.

3. Materials

   All patient contacting materials have not been used in legally marketed Olympus devices.

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G. Summary including a Brief Discussion of Non-clinical Tests and How their Results support Determination of Substantial Equivalence

1. Design

The Heat Probe Unit has been designed, manufactured and tested in compliance with Voluntary Safety Standards. It meets the requirements of IEC 60601-1 and IEC 60601-1-2, as well as CISPR 11.

2. Materials

The biocompatibility test reports of the above new materials show that such materials is complies with ISO 10993-1.

H. Summary including Conclusions drawn from Non-clinical Tests

When compared to the predicate device, the Heat Probe Unit HPU-20 and its accessories do not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 19 1998

Ms. Laura Storms-Tyler
Director, Regulatory Affairs
Olympus America Inc.
Two Corporate Center Drive
Melville, NY 11042-1179

Re: K982289
Heat Probe Unit HPU-20, accessories and probes
Dated: June 26, 1998
Received: June 30, 1998
Regulatory Class: II
21 CFR 876.4300/Procode: 78 KNS

Dear Ms. Storms-Tyler:

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) 594-4613. 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/dsma/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K982289

Indications for Use Statement

510(k) Number (if known): K982289

Device Name: **Olympus Heat Probe Unit HPU-20 and associated accessories**

Indications for Use:

Heat Probe Unit HPU-20

The Olympus Heat Probe Unit HPU-20 has been designed for thermal cautery with the Olympus Heat Probes.

Heat Probe CD-110## /120##

The Olympus Heat Probe has been specifically designed to thermo-cauterize bleeding sites within the gastrointestinal tract under endoscopic observation.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (per 21CFR 801.109) OR Over-the Counter Use _____ (Optional Format 1-2-96)

Robert R Watkins

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K982289