K983811

DEC 24 1998

510(k) Summary

Olympus Unipolar Optical Biopsy Forceps

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

Device Name: Olympus Unipolar Optical Biopsy Forceps

Common/Usual Name: Unipolar Optical Biopsy Forceps

Classification Name: Endoscopic Electrosurgical Unit and Accessories

Classification: CFR 876.4300 Class II

Predicate Devices:

Olympus	O5106	Rigid biopsy forceps with spoon jaw	K790071
Olympus	O5105	Rigid biopsy forceps, insulated	K790071
Olympus	O3109/A	Biopsy forceps with sharp cutting jaws	K790071
Olympus	O0115	Coagulation Electrode	K790071
Karl Storz	Biopsy Forceps, through cutting, double action jaws, for unipolar coagulation		unknown
Richard Wolf	Coagulating biopsy forceps by Tauber Type 8650.62		unknown

Prepared & Submitted by: Laura Storms-Tyler
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Summary Preparation Date: December 8, 1998

Statement of Intended Use:

The Olympus Unipolar Optical Biopsy Forceps has been designed for endoscopic biopsy and coagulation within the urinary tract.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 24 1998

Ms. Laura Storms-Tyler
Olympus Winter & Ibe GmbH
c/o Olympus America, Inc.
2 Corporate Center Drive
Melville, NY 11747

Re: K983811
Unipolar Optical Biopsy Forceps
Dated: October 27, 1997
Received: October 28, 1998
Regulatory Class: II
21 CFR 876.4300/Procode: 78 KGE

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 legally marketed predicate 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,

Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):

Device Name: OLYMPUS Unipolar Optical Biopsy Forceps

Indication for Use:

The OLYMPUS Unipolar Optical Biopsy Forceps has been designed for endoscopic biopsy and coagulation within the urinary tract.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Presciption Use ✓ OR Over-the Counter Use _____
(per 21CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983811