SEP 2 9 1999

OLYMPUS
WINTER & IBE
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510(k) SUMMERY

OLYMPUS WORKING ELEMENT FOR PROBES

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

Device Name: Olympus Working Element for Probes

Common/Usual Name: Working Element

Classification Name: ENDOSCOPE AND/OR ACCESSORIES.

Classification: CFR 876.1500 Class II

Subject Devices:

Model	Description
A2765	Working element, for probes
A0561	Guiding tube, for probes, with retractor
A0562	Guiding tube, for probes
A2891	Injection cannula, 1,2 mm x 420 mm

Predicate Devices:

Manufacturer	Description	510(k)
Richard Wolf	Working element with open handle and probe guide channel Type 8654.281	unknown
Richard Wolf	Injection cannula flexible, 4.5 Fr Type 8654.951	unknown
Olympus	Working element O3523	K790071
Olympus	Working element, V-spring type A3573	K904939
Olympus	Working element, V-spring type A2496	K904939
Olympus	Knife, semi circular, 3 Fr. channel, for A2496	K904939
Olympus	Stricture scalpel hollow, for use of a 5 Fr. guide catheter	K790071

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Prepared & Submitted By:
(Contact Person)

Mrs. Laura Storms-Tyler
Olympus America Inc.
Endoscope Division
Two Corporate Center Drive
Melville, NY 11747-3157
Phone: 516-844-5688
FAX: 516-844-5416

Summery Preparation Date: September 6, 1999

Statement of Intended Use:

The Olympus working element for probes (e.g. laser fibers), guiding tubes and injection cannula are intended to examine and to perform various diagnostic and therapeutic procedures in the urological tract.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 29 1999

Olympus Winter & IBE
c/o Mrs. Laura Storms-Tyler
Director, Regulatory Affairs
Olympus America, Incorporated
Endoscope Division
Two Corporate Center Drive
Melville, New York 11747-3157

Re: K992141
Olympus Working Element for Probes
Dated: September 8, 1999
Received: September 9, 1999
Regulatory Class: II
21 CFR §876.1500/Procode: 78 FDC

Dear Mrs. 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

510(k) Number (if known): K992141

Device Name: Olympus working element for probes, guiding tubes and injection cannula.

Indications for Use:

The Olympus working element for probes (e.g. laser fibers), guiding tubes and injection cannula are intended to examine and to perform various diagnostic and therapeutic procedures in the urological 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)

David A. Segman
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K992141