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K 980465

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510 (k) SUMMARY
OLYMPUS TJF-140R/JF-140R EVIS DUODENOVIDEOSCOPES

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 TJF-140R/JF-140R EVIS Duodenovideoscopes
Olympus MAJ-311/MAJ-411 Distal Covers.

Common/Usual Name: Olympus EVIS Duodenovideoscopes

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

Predicate Devices: Olympus TJF-140 EVIS Duodenovideoscope (K954451)
Olympus JF-140 EVIS Duodenovideoscope (K954451)
Olympus MH-880 Distal Cover (K954451)
Olympus MH-975 Distal Cover (K954451)

Prepared & Submitted By:
(Contact Person)
Ms. Laura Storms-Tyler
Olympus America Inc.
Endoscope Division
Two Corporate Center Drive
Melville, New York 11747-3157
(516) 844-5688

Summary Preparation Date: 10/31/97

Statement of Intended Use:

TJF-140R/JF-140 R Duodenovideoscopes

Olympus TJF-140R/JF-140R Duodenovideoscopes have been designed to be used with an Olympus EVIS Video System Center, light source, documentation equipment, video monitor, Endo-Therapy Accessories (Forceps, Brush, Electrosurgical Accessories, etc.), Electrosurgical Unit, and other Ancillary Equipment for endoscopy and endoscopic surgery within the duodenum.

MAJ-311/MAJ-411 Distal Covers

The Olympus MAJ-311 Distal Cover is designed to be attached to the Olympus TJF-140R Duodenovideoscope during an endoscopic procedure. The Olympus MAJ-411 Distal Cover is designed to be attached to the Olympus JF-140R Duodenovideoscope during an endoscopic procedure.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 21 1998

Ms. Laura Storms-Tyler
Director, Regulatory Affairs
Endoscope Division
Olympus America, Inc.
Two Corporate Center Drive
Melville, NY 11747-3157

Re: K980465
Olympus TJF-140R and JF-140R EVIS Duodenoscopes
and MAJ 311-MAJ 411 Distal Tip Covers
Dated: February 2, 1998
Received: February 5, 1998
Regulatory Class: II
21 CFR 876.1500/Procode: 78 FDT

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

K980465

Indications for Use Statement

510(k) Number (if known): Not assigned yet

Device Name: Olympus TJF-140R/JF-140R EVIS Duodenovideoscopes and accessories

Indications for Use:

TJF-140R/JF-140R Duodenovideoscopes

Olympus TJF-140R/JF-140R Duodenovideoscopes have been designed to be used with an Olympus EVIS Video System Center, light source, documentation equipment, video monitor, Endo-Therapy Accessories (Forceps, Brush, Electrosurgical Accessories, etc.), Electrosurgical Unit, and other Ancillary Equipment for endoscopy and endoscopic surgery within the duodenum.

MAJ-311/MAJ-411 Distal Covers

Olympus MAJ-311 Distal Cover is specifically designed to be attached to the Olympus TJF-140R Duodenovideoscope during an endoscopic procedure. Olympus MAJ-411 Distal Cover is specifically designed to be attached to the Olympus JF-140R Duodenovideoscope during an endoscopic procedure.

(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 D. Nathan
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K980465