APR 1 6 2003

SMDA 510(k) SUMMARY

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

1. Manufacturer of the subject device

Name & Address of manufacturer:	Olympus Optical Co., Ltd. 2-3-1 Shinjyuku Monolis Nishi-Shinjuku, Shinjyuku-ku Tokyo, Tokyo 163-0914 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 426-42-5177 FAX 426-46-5613

B. Name of Contact Person

Name: Address, Phone and Fax Numbers:	Ms. Laura Storms-Tyler Olympus America Inc. Two Corporate Center Drive Melville, New York 11747-3157 TEL: (631) 844-5688 FAX: (631) 844-5554

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

Trade Name:	Pancreatic Drainage Tube
Common Name:	Stent
Classification:	21CFR #876.5010 Biliary catheter and accessories 21CFR #876.1500 Endoscope and accessories
Predicate Device:	Olympus PBD Stents #K933200 Zimmon Endoscopic Pancreatic Stent (K900923 Wilson-Cook Medical, Inc.)

D. Description of the Device(s)

Pancreatic Drainage Tube has been designed to be used with Olympus endoscopes for Endoscopic Pancreatic Drainage. The instrument consists of the Drainage Tube, and Insertion Kit and Guidewire. The Drainage Tube is not intended to be permanently implanted in the patient. The drainage Tube is intended for short-term implantation.

E. Intended Use of the Device(s)

Pancreatic Drainage Tube has been designed to be used with Olympus endoscopes for Endoscopic Pancreatic Drainage. The Drainage Tube is not intended to be permanently implanted in the patient. The Drainage Tube is intended for short-term implantation.

F. Summary including Conclusions drawn from Non-clinical Tests

When compared to the predicate device, the subject device does not add any significant changes in the 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

APR 16 2003

Ms. Tina Steffanie-Oak
Senior R.A. Analyst
Olympus America Inc.
2 Corporate Center Drive
MELVILLE NY 11747-3157

Re: K021672
Trade/Device Name: Pancreatic Drainage Tube
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: 78 FGE
Dated: March 7, 2003
Received: March 11, 2003

Dear Ms. Steffanie-Oak:

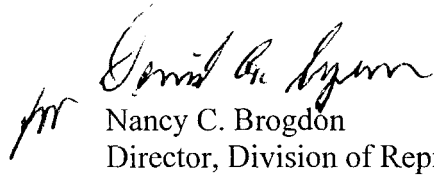
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note*: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration (21 CFR Part 807); listing (21 CFR Part 807), labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 the labeling regulation, please contact the Office of Compliance at (301) 594-4616. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number(if known): K021672

Device Name: Pancreatic Drainage Tube

Indications for Use:

This instrument has been designed to be used with Olympus endoscopes for Endoscopic Pancreatic Drainage. The Drainage Tube is not intended to be permanently implanted in the patient. The Drainage Tube is intended for short-term implantation. The Drainage Tube is also available as a kit, which includes accessories to aid in the placement of the Drainage Tube.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021672

(Optional Format 1-2-96)