JUN 1 9 2002

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510(k) SUMMARY
Olympus Ultrasonic Gastrovideoscope GF TYPE UC140P-DO5 and Ultrasonic Gastrofiberscope GF TYPE UC30P

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

1. Manufacturer of the subject devices

Name & Address of manufacturer:	Olympus Optical Co., Ltd. 2-3-1 Shinjyuku Monolis Nishishinjyuku Shinjuku-ku, Tokyo, 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)-46-5416

B. Name of Contact Person

Name: Address, Phone and Fax Numbers:	Ms. Laura Storms-Tyler Olympus America Inc. Director, Regulatory Affairs Two Corporate Center Drive Melville, New York 11747-3157 TEL: (631) 844-5474 FAX: (631) 844-5416

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

Device Name:	Olympus Ultrasonic Gastrovideoscope GF TYPE UC140P-DO5 and Olympus Ultrasonic Gastrofiberscope GF TYPE UC30P
Common Name:	Olympus Ultrasonic Gastrovideoscope and Olympus Ultrasonic Gastrofiberscope
Classification Name:	21 CFR876.1500 Endoscope and accessories

D. **Description of the Device(s)**

Olympus Ultrasonic Gastrovideoscope GF Type UC140P-D05

The Olympus GF-UC140P-D05 Ultrasonic Gastrovideoscope has been designed to be used with the AI5200S and Envision Plus Ultrasound Imaging Systems (Dornier Surgical Products, Inc.) Olympus EVIS Video System Center, Light Source, Endo-Therapy Accessories (such as Aspiration Biopsy Needles) and Electrosurgical Unit (except for the case of Endoscopic Ultrasound (EUS) guided Electrosurgery) for endoscopic ultrasonic imaging and treatment in the gastrointestinal wall, biliary and pancreatic ducts, and surrounding organs. These instruments also provide for Endoscopic Ultrasound (EUS) guided fine needle aspiration (FNA) of submucosal and extramural lesions of the gastrointestinal tract, i.e., pancreatic masses, mediastinal masses, and lymph nodes).

Olympus Ultrasonic Gastrofiberscope GF Type UC30P

The Olympus GF-UC30P Ultrasonic Gastrofiberscope has been designed to be used with the AI5200S and Envision Plus Ultrasound Imaging Systems (Dornier Surgical Products, Inc.) Olympus EVIS Video System Center, Light Source, Endo-Therapy Accessories (such as Aspiration Biopsy Needles) and Electrosurgical Unit (except for the case of Endoscopic Ultrasound (EUS) guided Electrosurgery) for endoscopic ultrasonic imaging and treatment in the gastrointestinal wall, biliary and pancreatic ducts, and surrounding organs. These instruments also provide for Endoscopic Ultrasound (EUS) guided fine needle aspiration (FNA) of submucosal and extramural lesions of the gastrointestinal tract, i.e., pancreatic masses, mediastinal masses, and lymph nodes).

E. **Intended Use of Device(s)**

The Olympus GF-UC140P-D05 Ultrasonic Gastrovideoscope has been designed to be used with the AI5200S and Envision Plus Ultrasound Imaging Systems (Dornier Surgical Products, Inc.) Olympus EVIS Video System Center, Light Source, Endo-Therapy Accessories (such as Aspiration Biopsy Needles) and Electrosurgical Unit (except for the case of Endoscopic Ultrasound (EUS) guided Electrosurgery) for endoscopic real-time ultrasound imaging, for performing EUS guided Fine Needle Aspiration (FNA) and for endoscopic surgery within the upper digestive tract.

Olympus Ultrasonic Gastrofiberscope GF Type UC30P

The Olympus Ultrasonic Gastrofiberscope GF Type UC30P has been designed to be used with the AI5200S and Envision Plus Ultrasound Imaging Systems (Dornier Surgical Products, Inc.) Olympus EVIS Video System Center, Light Source, Endo-Therapy Accessories (such as Aspiration Biopsy Needles) and Electrosurgical Unit (except for the case of Endoscopic Ultrasound (EUS) guided Electrosurgery) for endoscopic real-time ultrasound imaging, for performing EUS guided Fine Needle Aspiration (FNA) and for endoscopic surgery within the upper digestive tract.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 9 2002

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

Re: K021886
Trade/Device Name: Olympus Gastrovideoscope GF TYPE UC140P-DO5 and Olympus Ultrasonic Gastrofiberscope GF TYPE UC30P
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Product Code: 78 FDS
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasound transducer
Product Code: 78 ITX
Regulatory Class: II
Dated: May 7, 2002
Received: June 7, 2002

Dear Ms. Storms-Tyler:

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) that do not require approval of a premarket approval application (PMA). 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 (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 and 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 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

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

Enclosure

K021886

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021886

Indications for Use Statement

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

Device Name: Olympus Ultrasonic Gastrovideoscope GF TYPE UC140P-DO5
Olympus Ultrasonic Gastrofiberscope GF TYPE UC30P

Indications for Use:

Olympus Ultrasonic Gastrovideoscope GF TYPE UC140P-DO5

The Olympus GF-UC140P-DO5 Ultrasonic Gastrovideoscope has been designed to be used with the AI5200S and Envision Plus Ultrasound Imaging Systems (Dornier Surgical Products, Inc.), Olympus EVIS Video System Center, Olympus Light Sources, Olympus Endo-Therapy Accessories(such as Aspiration Biopsy Needles) and Olympus Electrosurgical Units(except for the case of Endoscopic Ultrasound (EUS) guided Electrosurgery) for performing real-time endoscopic ultrasound imaging, EUS guided Fine Needle Aspiration(FNA), and for endoscopic ultrasound guided or assisted intervention within the upper digestive tract.

Olympus Ultrasonic Gastrofiberscope GF TYPE UC30P

The Olympus GF-UC30P Ultrasonic Gastrofiberscope has been designed to be used with the AI5200S and Envision Plus Ultrasound Imaging Systems (Dornier Surgical Products, Inc.), Olympus Light Source, Olympus Endo-Therapy Accessories(such as Aspiration Biopsy Needles) and Olympus Electrosurgical Units(except for the case of Endoscopic Ultrasound (EUS) guided Electrosurgery) for performing real-time endoscopic ultrasound imaging, EUS guided Fine Needle Aspiration (FNA), and for endoscopic ultrasound guided or assisted intervention within the upper digestive tract.

(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

(Per21 CFR 801.109)

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