DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 1997

Subhash R. Patel
Regulatory Affairs Associate
Endoscope Division
OLYMPUS AMERICA, INC.
Two Corporate Center Drive
Melville, New York 11747-3157

Re: K971660
Olympus GF-UM130 Ultrasound Gastrovideoscope, its associated accessories and ancillary equipment
Dated: May 2, 1997
Received: May 6, 1997
Regulatory Class: II
21 CFR 876.1500/Procode: 78 FDS
21 CFR 892.1560/Procode: 90 IYO

Dear Mr. Patel:

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. You may, therefore, market the device, subject to the general controls provisions Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practices, 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 Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) 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, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's February 17, 1993 "Revised 510(k) Diagnostic Ultrasound Guidance for 1993." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your 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 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) 594-4591. 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 at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Mary Joan Cornelius at (301) 594-2194.

Sincerely yours,

Robert R Watkins /

for 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(s)

JUL 25 1997

K971660

510 (k) SUMMARY
OLYMPUS GF-UM 130 ULTRASOUND GASTROVIDEOSCOPE

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 GF-UM130 Ultrasound Gastrovideoscope
Common/Usual Name:	Ultrasound Gastroscope
Classification Name:	Class II, 21 CFR 876.1500 Endoscope and Accessories. Class II, 21 CFR 892-1560 Ultrasonic Pulsed Echo Imaging System
Predicate Devices:	Olympus GF-UM20 Ultrasound Gastroscope (K926514) Olympus GIF Type 140 Series Gastrovideoscopes (K954451)
Prepared & Submitted By: **(Contact Person)**	Mr. Subhash Patel Olympus America Inc. Endoscope Division Two Corporate Center Drive Melville, New York 11747-3157 (516) 844-5481
Summary Preparation Date:	05/02/97

Statement of Intended Use:

Olympus GF-UM130 Ultrasound Gastroscope has been designed to be used with an Olympus Endoscopic Ultrasound Center, EVIS Video System Center, light source, documentation equipment, video monitor, Endo-Therapy accessories and other ancillary equipment for endoscopic ultrasound imaging of the gastrointestinal wall, biliary and pancreatic duct, and surrounding organs.

K971660

Indications for Use Statement

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

Device Name: **Olympus GF-UM130 Ultrasound Gastrovideoscope, its associated accessories and ancillary equipment.**

Indications for Use:

Olympus GF-UM130 Ultrasound Gastroscope has been designed to be used with an Olympus Endoscopic Ultrasound Center, EVIS Video System Center, light source, documentation equipment, video monitor, Endo-Therapy accessories and other ancillary equipment for endoscopic ultrasound imaging of the gastrointestinal wall, biliary and pancreatic duct, and surrounding organs.

(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)

Peter R Rathmann

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K971660