DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

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

JUL 27 2015

Re: K002231
Trade/Device Name: Olympus LF-DP Gastrointestinal and Sigmoid Fiberscope
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDS, FCW, GCT
Dated (Date on orig SE ltr): December 12, 2000
Received (Date on orig SE ltr): December 13, 2000

Dear Ms. Storms-Tyler,

This letter corrects our substantially equivalent letter of January 30, 2001.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K002231

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

Device Name: Olympus LF-DP Gastrointestinal and Sigmoid Fiberscope

Indications for Use:

Olympus LF−DP Gastrointestinal and Sigmoid Fiberscope, accessories and ancillary equipment are inetend for observation of the upper and lower digestive tract including esophagus, stomach, and sigmoid colon.

(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)

Carolyn Y Neuland for Dan Schultz

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

(Optoinal Format 1-2-96)

510(k) Number K002231

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510(k) SUMMARY

LF-DP Gastrointestinal and Sigmoid Fiberscope, accessories and ancillary equipment

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR, Section807.92.

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

1. Manufacturer of the subject device

Name & Address of Manufacturer;	Olympus Optical Co,. Ltd. 2-3-1 Shinjuku Monolis Nishi-shinjuku Shinjuku-ku, Tokyo, 163-0914 Japan
Registration No :	810047
Address, Phone and Fax Number of R&D Department Endoscope Division	2951 Ishikawa-cho Hachioji-shi, Tokyo 192-8507 Japan TEL 81-426-42-5177 FAX 81-426-46-5613

2 Name of Contact Person

Name :	Ms.Laura Storms-Tyler Director, Regulatory Affairs Olympus America Inc.
Address, Phone and Fax	Olympus America Inc. Two Corporate Center Drive Melville, NY 11747-3157 TEL (631)844-5688 FAX (631)844-5416

B. Device Name, Common Name

1. Device Name :	LF-DP Gastrointestinal and Sigmoid Fiberscope, accessories and ancillary equipment.
2. Common/Usual Name :	Gastrointestinal and Sigmoid Fiberscope
3. Classification Name :	21CFR 876.1500 Class II

C. Predicate Devices :

# K981543	LF-DP Tracheal Intubation Fiberscopes, accessories and ancillary equipment

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D. Summary Description of the Device

1. Summary

The subject device, the LF-DP for use in the upper and lower digestive tract, is identical to the predicate device, the LF-DP Tracheal Intubation Fiberscope. The only difference between the subject and predicate devices is the indications for use. There are no other differences in design, materials or specifications. This does not affect the safety or efficacy of the subject.

2. Design

"LF-DP Gastrointestinal and Sigmoidfiberscope" has been designed, manufactured and tested in compliance with voluntary safety standards. It meets the requirements of IEC 60601-1, IEC60601-1-1, IEC60601-1-2, IEC60601-2-18.

3. Materials

There are no new patient-contacting materials.

E. Intended Use of the device

Except for expanding the intended use to include use within the upper and lower digestive, other characteristics of the Olympus LF-DP Gastrointestinal and Sigmoidfiberscope is identical to the Predicate Olympus LF-DP Tracheal Intubation.

F. Technological Characteristics

This endoscope does not have special technological characteristics, when compared to the predicate device.

G. Reason for not requiring clinical data

When compared to the predicate devices, "LF-DP Gastrointestinal and Sigmoidfiberscope" does not incorporate any significant change for safety and efficacy to the predicate device. Therefore clinical data is not necessary for its evaluation of safety and efficacy.