DEC 11 2012

510(k) SUMMARY

EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE
OLYMPUS GIF-XP190N

October 24, 2012

1 General Information

- Applicant: OLYMPUS MEDICAL SYSTEMS CORP.
  2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507
  Establishment Registration No: 8010047

- Official Correspondent: Sheri L. Musgnung
  Regulatory Affairs & Quality Assurance
  Olympus America Inc.
  3500 Corporate Parkway
  PO Box 610
  Center Valley, PA 18034-0610, USA
  Phone: 484-896-3147
  FAX: 484-896-7128
  Email: sheri.musgnung@olympus.com

- Manufacturer: Aizu Olympus Co., Ltd.
  500 Aza-Muranishi, Ooaza-Iidera, Monden-cho,
  Aizuwakamatsu-shi, Fukushima, Japan 965-8520
  Establishment Registration No.: 9610595

2 Device Identification

- Device Trade Name: EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-XP190N
- Common Name: GASTROINTESTINAL VIDEOSCOPE
- Regulation Number: 876.1500
- Regulation Name: Endoscope and Accessories
- Regulatory Class: II
- Classification Panel: Gastroenterology and urology
- Product Code: FDS (gastroscope and accessories, flexible/rigid)
  NWB (endoscope, accessories, narrow band spectrum)

3 Predicate Device Information

Subject Device (Part of this submission)	Predicate Device	Predicate Device 510(k) No.
EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF TYPE XP190N	EVIS EXERA II GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF TYPE XP180N	K100584

4 Device Description

The EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE, GIF-XP190N is an additional component of the EVIS EXERA III VIDEO SYSTEM.

The subject endoscope could be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), and other ancillary equipment within the upper digestive tract.

5 Indications for Use

EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-XP190N

This instrument is intended to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery.

The EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE GIF-XP190N is indicated for use transorally or transnasally within the upper digestive tract (including the esophagus, stomach, and duodenum).

6 Comparison of Technological Characteristics

The endoscope incorporates the following features compared to the predicate device: (1) A new Integrated scope connector that includes both the Light-guide and electronic-contact (video scope connection), (2) New nozzle, (3) Compatibility with High-Frequency Electrocautery.

7 Summary of non-clinical testing

Risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971:2007. The design verifications tests and their acceptance criteria were identified and performed as a result of this risk analysis assessment.

The software validation activities were performed in accordance with the FDA Guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The device software is considered a "Minor Level of Concern."

The following standards have been applied to the EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-XP190N of EVIS EXERA III VIDEO SYSTEM:

- IEC 60601-2-18
- IEC 60601-1-2
- ISO 14971

8 Conclusion

When compared to the predicate device, the EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-XP190N of the EVIS EXERA III VIDEO SYSTEM does not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 11, 2012

OLYMPUS MEDICAL SYSTEMS CORPORATION
% Ms. Sheri L. Musgnung
Regulatory Affairs & Quality Assurance
Olympus America, Inc.
3500 Corporate Parkway, P.O. Box 610
CENTER VALLEY PA 18034-0610

Re: K123317
Trade/Device Name: GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-XP190N
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDS, NWB
Dated: November 27, 2012
Received: November 28, 2012

Dear Ms. Musgnung:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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

Indications for Use

510(k) Number (if known): K123317

Device Name: GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-XP190N

Indications For Use:

GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-XP190N

This instrument is intended to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery.

The EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE GIF-XP190N is indicated for use transorally or transnasally within the upper digestive tract (including the esophagus, stomach, and duodenum).

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
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(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K123317