K123704
Page 1 of 3

510(k) SUMMARY

AUTOMATED ENDOSCOPE LEAK TESTER ALT-Y0003

FEB 4 2013

November 30, 2012

1 General Information

- Applicant:

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

- Official Correspondent:

Daphney Germain-Kolawole
Regulatory Affairs Project Manager
Regulatory Affairs & Quality Assurance
Olympus America Inc.
3500 Corporate Parkway
PO Box 610
Center Valley, PA 18034-0610, USA
Phone: 484-896-5691
FAX: 484-896-7128
Email: daphney.germain-kolawole @olympus.com

- Manufacturer:

SHIRAKAWA OLYMPUS CO., LTD.
3-1, Aza-Ookamiyama, Ooaza-Odakura, Nishigo-mura,
Nishishirakawa-gun, Fukushima, Japan 961-8061
Establishment Registration No: 3002808148

2 Device Identification

- Device Trade Name: AUTOMATED ENDOSCOPE LEAK TESTER ALT-Y0003
- Common Name: Leak Tester
- Regulation Number: 876.1500
- Regulation Name: Endoscope and accessories
- Regulatory Class: II
- Classification Panel: Gastroenterology and urology
- Product Code: PCV

3 Predicate Device Information

	PD1	PD2
■ Device Name:	Endoscope Leak Tester ZUTR-10003	Maintenance Unit MU-1
■ 510(k) No.	K093718	K051886
■ Manufacturer	Zutron Medical	SHIRAKAWA OLYMPUS CO., LTD.

4 Device Description

The subject ALT-Y0003 is used to detect leaks from Olympus flexible endoscopes. It utilizes two testing modes; one is automated leak test mode (ALT mode) and the other is manual leak test mode (MLT mode). In ALT mode, it is not required to soak the tested endoscope in water. The ALT-Y0003 detects leak from the difference of air pressure. The ALT-Y0003 can also be used for conventional manual leak test by soaking an endoscope in water. The ALT-Y0003 has an RFID function to recognize endoscope and operator identification. It can store test results in its internal memory and this stored record can be printed out with the designated printer and/or transferred to deginated USB memory.

5 Indications for Use

This equipment is intended to be used to perform and record leakage testing on Olympus flexible endoscopes.

6 Comparison of Technological Characteristics

The subject ALT-Y0003 is substantially equivalent to the predicate devices. Both the subject device and predicate devices are used for leak testing of endoscopes in combination with connecting tube by feeding air into endoscopes.

Compared to the predicate devices, the main differences of ALT-Y0003 are as follows:

- Automated leak test mode
- RFID
- Internal memory to store test results

It has been confirmed that the ALT mode has equivalent detecting rate to conventional MLT in nonclinical testing. The subject device was also tested in compliance with electrical safety standard, EMC standard, and FCC Part 15 standard and confirmed there is no problem with safety and effectiveness.

7 Summary of Nonclinical Testing

Performance testing was conducted to confirm that the leak detecting rate of ALT is equivalent to that of conventional MLT. It has been demonstrated that there is no significant difference in leak detection rates between ALT and conventional MLT. Also, it has been confirmed that the detection threshold of the ALT-Y0003 can detect a leak which actually causes a water leak.

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."

As the ALT-Y0003 is considered to be an intentional radiator prescribed under Federal Communications Commission (FCC) 47 CFR Part 15 – Radio Frequency Devices, Subject C – Intentional Radiators, it has been evaluated to verify compliance with this regulation.

Basic safety and performance testing was performed in accordance with IEC 61010-1 and IEC 61326-1. In addition, verification was conducted to evaluate the mechanical and functional performance.

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 following standards have been applied to ALT-Y0003

- IEC 61010-1: 2001
- IEC 61326-1: 2005
- ISO 14971: 2007

8 Conclusion

When compared to the predicate devices, the AUTOMATED ENDOSCOPE LEAK TESTER ALT-Y0003 does not incorporate any significant changes in intended use, method of operation 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 20993-0002

February 4, 2013

OLYMPUS MEDICAL SYSTEMS CORP.
% Ms. Daphney Germain-Kolawole
Regulatory Affairs Project Manager
Olympus America, Inc.
3500 Corporate Parkway
CENTER VALLEY PA 18034-0610

Re: K123704
Trade/Device Name: AUTOMATED ENDOSCOPE LEAK TESTER ALT-Y0003
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: PCV
Dated: November 30, 2012
Received: December 3, 2012

Dear Ms. Germain-Kolawole:

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): K123704

Device Name: AUTOMATED ENDOSCOPE LEAK TESTER ALT-Y0003

Indications For Use:

This equipment is intended to be used to perform and record leakage testing on Olympus flexible endoscopes.

Prescription Use_____ AND/OR Over-The-Counter Use ✓
(Part 21 CFR 801 Subpart D) (21 CFR 801 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
2013.02.05 13:00:05 -05'00'

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K123704