

ENDOSCOPE POSITION MARKING PROBE  
ENDOSCOPE POSITION DETECTING UNIT  
Olympus Medical Systems, Corp.

Traditional 510(k) Notification  
December 27, 2013

MAR - 7 2014

## 510(k) SUMMARY

### UPD-3 ENDOSCOPE POSITION DETECTING UNIT MAJ-1878 ENDOSCOPE POSITION MARKING PROBE

#### I. 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  
Olympus Corporation of the Americas  
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  
Registration Number: 3002808148  
  
AIZU OLYMPUS CO., LTD.  
500 Aza Muranishi Ooaza-lidera  
Monden-cho  
Aizuwakamatsu-Shi Fukushima, JAPAN 965-8520  
Registration Number: 9610595

#### II. Device Identification <MAJ-1878>

- Device Trade Name: MAJ-1878
- Common Name: ENDOSCOPE POSITION MARKING PROBE
- Regulation Number: 876.1500

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- Regulation Name: Endoscope and Accessories
- Regulatory Class: II
- Classification Panel: Gastroenterology and urology
- Product Code: PGU  
FDA  
FDF

**II. Device Identification <UPD-3>**

- Device Trade Name: UPD-3
- Common Name: ENDOSCOPE POSITION DETECTING UNIT
- Regulation Number: 876.1500
- Regulation Name: Endoscope and Accessories
- Regulatory Class: II
- Classification Panel: Gastroenterology and urology
- Product Code: PGU  
FDA  
FDF

**III. Predicate Device Information**

MAJ-1878		
Model name	Applicant	510(k) No.
Probe XB01-657-6	Olympus Optical Co., Ltd.	K002749
UPD-3		
Model name	Applicant	510(k) No.
ENDOSCOPE POSITION DETECTING UNIT UPD-Y0003	OLYMPUS MEDICAL SYSTEMS CORP.	K103312

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#### IV. Device Description

<MAJ-1878&UPD-3>

The Endoscope Position Detecting Unit (UPD-3) has been designed to be used with Olympus endoscope systems and Endoscope Position Marking Probe (MAJ-1878) for the detection and display of the shape of an endoscope once inserted into the patient. The UPD-3 detects the magnetic field generated by magnetic coils built directly into the endoscope or the MAJ-1878 inserted into the endoscope's instrument channel. The position coordinate of each coil is computed by carrying out arithmetic processing and is displayed on the UPD-3 monitor.

The system is used in patients who require colonoscopy and enteroscopy except patients with a critical active implantable device such as a pacemaker and an implantable cardioverter defibrillator or pregnant women.

No modifications were made to the technology, performance, and specifications for the subject UPD-3 in comparison to the predicate device (K103312).

#### V. Indications for Use

<MAJ-1878>

This instrument has been designed to be used with an Olympus endoscope and the endoscope position detecting unit for detection and display of the location and/or shape of the inserted endoscope.

<UPD-3>

This instrument has been designed to be used with Olympus endoscope systems for the detection and display of the shape of an endoscope once inserted into the patient.

<Patient population>

Patients who require colonoscopy and enteroscopy except as follows:  
Patients with a critical active implantable device such as a pacemaker and an implantable cardioverter defibrillator  
Pregnant women

#### VI. Comparison of Technological Characteristics

<MAJ-1878>

The addition of the device to be used in the small intestine does not affect the safety and effectiveness.

The following design specifications have been modified and do not affect the safety and effectiveness of the device.

- Materials
- Dimensions
- Applicable method of reprocessing

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< UPD-3 >

There is no technological difference between the subject device and the predicate device; however, the modification on the subject device's software has been made to include additional minor software features, and it does not affect the safety and effectiveness.

## VII. Summary of non-clinical testing

The differences of technological characteristics between the predicate device and the subject device are confirmed that they are substantially equivalent through the following tests and standards.

- Bench test of small intestine model.
- Risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971:2007. The design verification 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.

Biocompatibility testing is performed in accordance with the FDA Guidance, "Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices, Blue Book Memo, G95-1".

The validation test on the reprocessing has been performed in accordance with the FDA guidance "Labelling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance - April 1996". The FDA guidance "Draft Guidance for Industry and FDA Staff - Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling – May 2011" was also taken into consideration.

The following standards have been applied to the MAJ-1878&UPD-3:

- IEC 60601-1
- IEC 60601-1-1
- IEC 60601-2-18
- IEC 60601-1-2
- ISO 14971
- IEEE Std C95.1(only UPD-3)

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### **VIII. Conclusion**

When compared to the predicate device, the MAJ-1878 & UPD-3 do not incorporate any significant changes in intended use, method of operation, or design that could affect the safety or effectiveness of the device.



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

March 7, 2014

OLYMPUS MEDICAL SYSTEMS CORP.  
% Daphney Germain-Kolawole  
Regulatory Affairs Project Manager  
Olympus Corporation of the Americas, Inc.  
3500 Corporate Parkway PO Box 610  
Center Valley, PA 18034-0610

Re: K134026  
Trade/Device Name: ENDOSCOPE POSITION MARKING PROBE and  
ENDOSCOPE POSITION DETECTING UNIT  
Regulation Number: 21 CFR§ 876.1500  
Regulation Name: Endoscope and accessories  
Regulatory Class: II  
Product Code: PGU, FDA, FDF  
Dated: December 27, 2013  
Received: December 30, 2013

Dear Daphney 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)

K134026

Device Name

ENDOSCOPE POSITION DETECTING UNIT

Indications for Use (Describe)

<UPD-3>

This instrument has been designed to be used with Olympus endoscope systems for the detection and display of the shape of an endoscope once inserted into the patient.

<Patient population>

Patients who require colonoscopy and enteroscopy except as follows:  
Patients with a critical active implantable device such as a pacemaker and  
an implantable cardioverter defibrillator  
Pregnant women

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Benjamin R. Fisher -S

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**Indications for Use**

510(k) Number (if known)

K134026

Device Name

ENDOSCOPE POSITION MARKING PROBE

Indications for Use (Describe)

This instrument has been designed to be used with an Olympus endoscope and the endoscope position detecting unit for detection and display of the location and/or shape of the inserted endoscope.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Benjamin R. Fisher, S  
2014.03.07 16:57:28 -05'00'