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: K984358
Trade/Device Name: Olympus Distal Attachment (MH and MAJ Models) for Endoscopic Mucosal Resection
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDS
Dated (Date on orig SE ltr): August 31, 1999
Received (Date on orig SE ltr): September 2, 1999

Dear Ms. Storms-Tyler,

This letter corrects our substantially equivalent letter of September 17, 1999.

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

510(k) Number (if known): K 984358

Device Name: Olympus Distal Attachment

Indications for Use: The Olympus Distal Attachment is intended to be used for the following:

a) for use with electrosurgical snares for endoscopic mucosal resection within the gastrointestinal tract; and
b) for use in keeping the suitable depth of endoscopic field of view.

Concurrence of CDRH, Office of Device Evaluation ODE

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K984358

(Optional Format 1-2-96)

SEP 17 1999

K984358 /S1

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510(k) SUMMARY
OLYMPUS DISTAL ATTACHMENT

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

1. Manufacturer of the subject devices

Name & Address of manufacturer:	Olympus Optical Co., Ltd. 22-2 Nishi-Shinjuku, 1-Chome, Shinjuku-ku, Tokyo 163-8610 Japan
Registration No.:	8010047
Address, Phone and Fax Numbers : of R&D Department, Endoscope Division	2951 Ishikawa-Cho, Hachioji-shi, Tokyo 192-8507 Japan TEL 0426-42-5101 FAX 0426-46-2786

B. Name of Contact Person

Name:	Laura Storms-Tyler
Address, Phone and Fax Numbers :	Olympus America Inc. Endoscope Division Two Corporate Center Drive Melville, New York 11747-3157 TEL: (516) 844-5688 FAX: (516) 844-5416

C. Trade Name, Common Name and Classification Name

Trade Name: Olympus Distal Attachment MH-462, -463, -464, -465, -466, -483, -587, -588, -589, -590, -591, -592, -593, -594, -594, -595, -596, -597, -598,
MAJ-289, -290, -291, -292, -293, -294, -295, -296, -297

Common Name : Transparent Cap

Classfication Name: 21CFR 876.1500, Class II, Endoscope and accessories

D. Legally Marketed Device(s) which we claim Substantial Equivalence

Manufacturer	Device Description	510(k)#
Olympus	MH-189	K954451 (Endoscope Accessory for Model CF-140S, CF-Q140L/I and CF-140L/I)

E. Description of the Device(s)

Olympus Distal Attachment has the shape of short transparent tube. Olympus Distal Attachment is to be attached to the distal end of the endoscope to facilitate endoscopic therapy.

F. Intended Use of the Device(s)

Olympus Distal Attachment has been designed to be attached to the distal end of the endoscope to facilitate endoscopic therapy. Olympus Distal Attachment is used for the followings.

1. Gastrointestinal mucosal resection (endoscopic mucosal resection)
2. Keeping the suitable depth of endoscope's view field
3. Helping the endoscope with being inserted into the gastrointestinal tract.

G. Summary of the Technological Characteristics of the Device compared to the Predicate Device(s)

1. Design

In order to maintain the electrical safety, the cap length of the subject devices is longer than the predicate MH-189.

2. Materials

All the patient contacting materials have not been used in Olympus legally marketed Devices.

H. Summary including a Brief Discussion of Determination of Substantial Equivalence

1. Design

The cap length supplies distance enough for the endoscopic therapy using the electrosurgical snares.

2. Materials

The biocompatibility test reports show that new materials does not cause a problem.

I. Summary including Conclusions drawn from Non-clinical Tests

When compared to the predicate device, the subject devices do not incorporate any significant change that could affect the safety or effectiveness.