DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 12, 2016

Olympus Medical Systems Corp.
% Sheri Musgnung
Manager, Regulatory Affairs
Olympus Corporation of the Americas
3500 Corporate Parkway, PO Box 610
Center Valley, PA 18034-0610

Re: K153625
Trade/Device Name: Single Use Injector NM600/610
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FBK
Dated: December 16, 2015
Received: December 18, 2015

Dear Sheri 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 contact the Division of Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Herbert P. Lerner -S

for 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K153625

Device Name
Single Use Injector NM600/610

Indications for Use *(Describe)*
This instrument has been designed to be used with an Olympus endoscope to perform endoscopic vascular or submucosal injection in the GI tract.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K153625

510(k) Summary

510(k) SUMMARY
Single Use Injector NM600/610

December 16, 2015

5.1 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
Olympus Corporation of the Americas
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:
Aomori Olympus Co., Ltd.
248-1 Okkonoki 2-chome Kuroishi-shi,
Aomori, Japan 036-0357
Establishment Registration No.: 9614641

5.2 Device Identification

■ Device Trade Name: Single Use Injector NM600/610

■ Common Name: Injector

■ Regulation Number: 876.1500

■ Regulation Name: Endoscope and accessories

■ Regulatory Class: II

■ Classification Panel: Endoscopic Injection Needle, Gastroenterology-Urology

■ Product Code: FBK

5.3 Predicate Device Information

Device Trade Name	Common Name	Applicant	510(k) No.
Olympus Injector NM-4-1, NM-5-1, NM-6-1, NM-7-1, NM-8-1, NM-9-1, NM-4U-1, NM-4Z-1	Injector	OLYMPUS OPTICAL Co., Ltd.	K011484
NM Injection Needles	Sterile Injection Needle	OLYMPUS Corporation.	K902736
Injection Needle	Injection Needle	ENDOCHOICE, INC.	K132065

5.4 Device Description

This instrument has been designed to be used with an Olympus endoscope to perform endoscopic vascular or submucosal injection in the GI tract.

The subject device consists of a handle section, needle section, and sheath section. The subject device is used to puncture the target tissue where guided by the endoscope. The fluid is injected to the target through the subject device by an injector which is connected the subject device.

5.5 Indications for Use

This instrument has been designed to be used with an Olympus endoscope to perform endoscopic vascular or submucosal injection in the GI tract.

5.6 Comparison of Technological Characteristics

Compared to the predicate device, the proposed subject device; Single Use Injector NM600/610, has similar technological characteristics. There is no significant difference that affects the safety or effectiveness of the subject device.

5.7 Summary of non-clinical testing

·The following performance testing was conducted to demonstrate the basic performance of the subject device and confirmed that the subject device performs as intended.

1, Inserting into endoscope
2, Withdrawing from endoscope
3, Advance of tube
4, Retraction of tube
5, Needle extension length
6, Smooth puncturing of the needle
7, Normal reaction force to needle puncturing.
8, Amount of injected fluid
9, Needle retraction propriety
10, Performance after repeated device operation
11, Visual inspection of the package
12, Peel strength of the package
13, Endurance to splitting of the package
14, Integrity of the package

·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.

·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 following standards have been applied to the Single Use Injector NM600/610.

·ISO 10993-1
·ISO 10993-5
·ISO 10993-10
·ISO 10993-11
·ASTM F756-13
·ISO 11135
·ISO 14971
·ASTM F1980-07

5.8 Conclusion

When compared to the predicate device, the Single Use Injector NM600/610 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.