April 28, 2020

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: K192498
Trade/Device Name: Single Use Injector NM-221C-0427
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FBK
Dated: March 19, 2020
Received: March 20, 2020

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Martha W. Betz, Ph.D.
Acting Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192498

Device Name

Single Use Injector NM-221C-0427

Indications for Use *(Describe)*

This instrument has been designed to be used with an Olympus endoscope to deliver injectable materials into the urinary bladder wall during the transurethral endoscopic procedures.

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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March 19, 2020

Revised 510(k) Summary

1 GENERAL INFORMATION

■ 510(k) Submitter: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Japan

■ Contact Person: Sheri L. Musgnung
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3500 Corporate Parkway PO Box 610
Center Valley, PA 18034-0610, USA
Phone: 484-896-3147
Fax: 484-896-7128
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■ Manufacturing site: Aomori Olympus Co., Ltd.
2-248-1 Okkonoki, Kuroishi-shi, Aomori 036-0357, Japan

2 DEVICE IDENTIFICATION

■ Device Name: Single Use Injector NM-221C-0427
■ Common Name: endoscopic injection needle, gastroenterology-urology
■ Regulation Number: 21 CFR 876.1500
■ Regulation Name: Endoscope and accessories
■ Regulatory Class: II
■ Product Code: FBK
■ Classification Panel: Gastroenterology/Urology

3 PREDICATE DEVICE

■ **Predicate device**

Device name	510(k) Submitter	510(k) No.
BONEE NEEDLE FOR BLADDER INJECTIONS NBI070	COLOPLAST A/S	K090217

4 DEVICE DESCRIPTION

■ General Description of the subject device

This instrument has been designed to be used with an Olympus endoscope to deliver injectable materials into the urinary bladder wall during the transurethral endoscopic procedures. The subject device is sterilized and packaged in a sterilization package.

■ Principle of Operation

When the operation portion of the needle section is pushed into the Sheath section, the needle protrudes from the distal end of the sheath section. Pulling the operation portion of the needle section toward the proximal end with respect to the sheath section pulls the needle into the coil sheath. The subject device is inserted into the endoscope in the retracted state. After the subject device reaches the urinary bladder wall, puncture is performed with the needle protruding from the coil sheath. A commercially available marketed syringe (not included in the subject device) is attached to the proximal end of the needle section to deliver injectable materials to the target site of the urinary bladder wall.

5 INDICATIONS FOR USE

This instrument has been designed to be used with an Olympus endoscope to deliver injectable materials into the urinary bladder wall during the transurethral endoscopic procedures.

6 COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE DEVICE

The NM-221C-0427 has the same technological characteristics and design as the predicate device except for the following new features:

- Needle design
- Sheath design
- Working length

Validation from non-clinical testing demonstrated that these technological features do not raise any new issues of safety or effectiveness of the subject device.

A side by side comparison of the subject device and the predicate device is provided below.

Item	Subject Device Single Use Injector NM-221C-0427	Predicate Device BONEE NEEDLE FOR BLADDER INJECTIONS NBI070
Indications for Use	This instrument has been designed to be used with an Olympus endoscope to deliver injectable materials into the urinary bladder wall during the transurethral endoscopic procedures.	The Bonee Needle for Bladder Injections is used to deliver injectable materials into the urinary bladder wall during the transurethral endoscopic procedures.
Regulation Number	21 CFR 876.1500	21 CFR 876.1500
Regulation Name	Endoscope and accessories	Endoscope and accessories
Regulatory Class	II	II
Product Code	FBK	FBK
Classification Panel	Gastroenterology/Urology	Gastroenterology/Urology
Compatible Olympus cystoscope	Working length: less than 380mm Channel inner diameter: 2.0mm or more	Working length: unknown Channel inner diameter: 5 French(= 1.7mm) or more
Needle width	27G	22G
Typical needle length	4mm	4mm
Maximum insertion portion diameter	φ1.84mm	unknown
Working length	971 mm	700mm
Sheath type	Sheath structure: dual structure (outer: coil sheath, inner: tube sheath)	Sheath structure: single structure (tube sheath only)
Stylet	Equipped (Diameter: φ0.3mm, Length: 700mm)	Not equipped
Tip shape of needle	Tip shape: Lancet Point	Tip shape: Unknown

7 PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

1) Sterilization/Shelf-life testing

Sterilization/shelf-life testing for the NM-221C-0427 were conducted in accordance with the FDA's Guidance for Industry and Food and Drug Administration Staff, "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile".

Accelerated aging test for the NM-221C-0427 was conducted in accordance with ASTM F1980-16, the standard guide for accelerated aging of sterile barrier systems for medical devices. The real-time aging test for three-years will be performed to demonstrate longer stability and support the results of the accelerated aging test.

2) Biocompatibility testing

Biocompatibility testing for the NM-221C-0427 were conducted in accordance with the FDA's Guidance for Industry and Food and Drug Administration Staff, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process". The Single Use Injector NM-221C-0427 is considered an externally communicating medical device in contact with Tissue/bone/dentin. The contact duration is limited exposure (i.e. contact is up to 24 hours). The biocompatibility testing included the following tests:

- Cytotoxicity Study Using the Colony Assay
- ISO Intracutaneous Study in Rabbits
- ISO Guinea Pig Maximization Sensitization Test
- ISO Acute Systemic Toxicity Study in Mice
- USP Rabbit Pyrogen Study, Material Mediated

3) Performance testing - Bench

Bench testing for the NM-221C-0427 as listed below was conducted to ensure that the subject device performs as intended and meet design specifications.

- Endoscope compatibility
- Needle slidability
- Puncture performance
- Liquid leakage
- Durability
- Flow rate (BS EN 1618: 1997 Catheters other than intravascular catheters – Test methods for common properties)
- Corrosion Testing (ISO 9626: 2016 Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods)

4) Performance testing - Animal

No animal study was performed to demonstrate substantial equivalence.

5) Performance testing - Clinical

No clinical study was performed to demonstrate substantial equivalence.

6) Risk analysis

Risk analysis for the NM-221C-0427 was conducted 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.

8 CONCLUSIONS

Based on the indications for use, technological characteristics, performance testing and technological comparison to the predicate device, the NM-221C-0427 raise no new issue of safety and effectiveness and are substantially equivalent to the predicate device in terms of safety, effectiveness and performance.