October 16, 2025

Olympus Medical Systems Corporation
% Jillian Connery
Program Manager Regulatory Affairs
Olympus Surgical Technologies of America
800 West Park Drive
Westborough, Massachusetts 01581

Re: K252247
Trade/Device Name: Injector Force Max Single Use Injector (NM-400L); Injector Force Max Single Use Injector (NM-400U); Injector Force Max Single Use Injector (NM-400Y); Injector Force Max Single Use Injector (NM-401L)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FBK
Dated: July 18, 2025
Received: July 18, 2025

Dear Jillian Connery:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Shanil P. Haugen -S

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252247

Please provide the device trade name(s).

Injector Force Max Single Use Injector (NM-400L);
Injector Force Max Single Use Injector (NM-400U);
Injector Force Max Single Use Injector (NM-400Y);
Injector Force Max Single Use Injector (NM-401L)

Please provide your Indications for Use below.

The Single Use Injector NM-400/401 Series is intended to be used to perform endoscopic vascular or submucosal injection in the digestive tract with an endoscope.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

SINGLE USE INJECTOR

510(k) SUMMARY

510(k) Summary: K252247

1. COMPANY INFORMATION

• Applicant

OLYMPUS MEDICAL SYSTEMS CORPORATION
2951 Ishikawa-cho, Hachioji-shi
Tokyo 192-8507, Japan
FDA Establishment Registration #: 8010047

• Official Correspondent

Jillian Connery
c/o Olympus Surgical Technologies of the Americas
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Cell: 404-542-5854
Email: jillian.connery@olympus.com

• Manufacturing Site
Olympus Vietnam Company Limited
8 Street
Long Thanh Industrial Zone, Tam An Commune
Long Thanh District Dong Nai, VN 810000
FDA Establishment Registration #; 3008040402

• **Date Prepared:** 04-Sep-2025

2. PRODUCT INFORMATION

- Trade Name: Single Use Injector
- Models: NM-400L-0421/0423/0425/0523/0525/0621/0623/0625
  NM-400U-0323/0423/0425/0523/0525/0623/0625
  NM-400Y-0423, NM-401L-0423/0425/0523/0525/0623/0625
- Common Name: Injector
- Classification Name: Endoscope and Accessories
- Product Code: FBK

- Regulation Number: 21 CFR 876.1500
- Regulation Name: Endoscope and accessories
- Device Class: II

3. PREDICATE DEVICE

- Trade Name: Single Use Injector
- Model: NM-600/610
- 510(k) Number: K153625

4. REFERENCE DEVICES

- Trade Name: Injection Needles
- Model: NM-10L/11L/12L/13L/14L/15L/16L/17L
- 510(k) Number: K902736

- Trade Name: Olympus Injector
- Model: NM-4L-1/5L-1/6L-1/7L-1/8L-1/9L-1
- 510(k) Number: K011484

5. DEVICE DESCRIPTION

The Olympus Single-Use Injector NM-400/NM-401 is a sterile, disposable injection needle designed for use with Olympus endoscopes to perform endoscopic vascular or submucosal injections in the digestive tract. The device comprises a handle section, needle section, and sheath section, and operates via a slider mechanism that extends and retracts the needle. The needle is connected to an injection port through which fluids can be delivered to targeted tissue. The NM-400/NM-401 series includes various models with needle gauges ranging from 21G to 25G and working lengths from 1650 mm to 2700 mm, accommodating different clinical needs and endoscope compatibilities. The device is constructed from biocompatible materials including stainless steel (SUS304), polypropylene (PP), and perfluoroalkoxy (PFA), and is sterilized using ethylene oxide (EtO). It is intended for single use only.

6. INDICATIONS FOR USE

The Single Use Injector NM-400/401 Series is intended to be used with an Olympus endoscope to perform endoscopic vascular or submucosal injection in the digestive tract.

7. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The Olympus NM-400/NM-401 and NM-600/610 injection needles are technologically similar in many core aspects.
Both are intended for endoscopic vascular or submucosal injection in the digestive tract and are classified as Class II medical devices under 21 CFR 876.1500 with the FDA product code FBK. They are designed for single use and are sterilized using ethylene oxide (EtO). Both devices are compatible with endoscopes and support a range of needle gauges and working lengths suitable for various clinical applications.

Despite these similarities, the NM-400/NM-401 introduces several enhancements and modifications. It offers both lancet bevel and flat bevel needle shapes, whereas the NM-600/610 only features lancet bevel needles. The NM-400/401 also includes models with smaller maximum insertion diameters (as small as 1.9 mm) compared to the 2.6 mm diameter of the NM-600/610, allowing compatibility with endoscopes that have smaller working channels. Additionally, the NM-400/401 includes a longer working length option of 2700 mm, which is not available in the predicate device. Material differences are also present. The NM-400/401 uses polypropylene (PP) for the outer tube and perfluoroalkoxy (PFA) for the inner tube, while the NM-600/610 uses polytetrafluoroethylene (PTFE) for both. These changes have been evaluated through biocompatibility testing to ensure safety. The handle design of the NM-400/NM-401 is more ergonomic and less bumpy than that of the predicate, although the operational mechanism remains the same. Furthermore, the NM-400/NM-401 uses a different packaging film material, which has been tested to confirm seal integrity and sterility maintenance.

A comparison of the subject and predicate device technological characteristics is provided below.

Feature	NM-400/NM-401	NM-600/610
Intended Use	Endoscopic vascular or submucosal injection in the digestive tract	Same
FDA Classification	Class II, 21 CFR 876.1500, Product Code FBK	Same
Sterilization	Ethylene oxide (EtO), single-use	Same
Endoscope Compatibility	Compatible with Olympus endoscopes	Same

Feature	NM-400/NM-401	NM-600/610
Needle Options	Lancet bevel and flat bevel	Lancet bevel only
Insertion Diameter	As small as 1.9 mm	2.6 mm
Working Length	Up to 2700 mm	Shorter length only
Tube Materials	Outer: Polypropylene (PP); Inner: Perfluoroalkoxy (PFA)	Both Inner and Outer: Polytetrafluoroethylene (PTFE)
Biocompatibility	Tested and confirmed	Tested and confirmed
Handle Design	More ergonomic and streamlined	Bulkier, less ergonomic
Packaging Material	Different film, tested for seal integrity and sterility	Different material (not specified)
Operational Mechanism	Same basic mechanism	Same

In summary, while the NM-400/NM-401 maintains the same fundamental design and intended use as the NM-600/610, it incorporates improvements in needle design, material composition, dimensional flexibility, and ergonomic features, all supported by appropriate performance and safety testing.

8. PERFORMANCE DATA

The following performance bench tests were conducted on the Olympus Single-use Injection Needle NM-400/NM-401 to demonstrate substantial equivalence to the predicate device and verify design integrity, including simulated distribution and accelerated aging:

1. Insertion into and Withdrawal from an Endoscope
2. Needle Advancement from the Tube
3. Needle Retraction into the Tube
4. Needle Puncture
5. Needle Return during Needle Puncture
6. Repeated Device Operations
7. Fluid Supply

8. Resistance to Corrosion (performed only on non-aged samples per ISO 9626)

These tests were performed on final, sterilized devices and included both baseline (T=0) and accelerated aged (T=3 years) samples. All tests met their predefined acceptance criteria, confirming the device's performance and stability over its intended shelf life.

9. BIOCOMPATIBILITY

The biocompatibility testing for the Olympus Single Use Injector (NM-400/NM-401 series) included evaluations for cytotoxicity, sensitization, irritation, acute systemic toxicity, material mediated pyrogenicity, and hemocompatibility, all of which passed according to ISO 10993 standards. Testing confirmed the device is non-cytotoxic, non-sensitizing, non-irritating, non-pyrogenic, non-hemolytic, and not acutely toxic. Additional chemical characterization and toxicological risk assessments support the conclusion that the device is biologically safe and stable over its intended shelf life.

10. STERILIZATION AND SHELF LIFE

The shelf life of the Olympus Single-use Injection Needles NM-400/401 series has been validated for three years through accelerated aging and package integrity testing in accordance with ASTM F1980-21 and ISO 11607-1/2:2019. Accelerated aging was conducted at 60°C for 162 days to simulate three years of real-time storage, with a real-time aging study also initiated. Post-aging performance testing confirmed that the devices maintained functionality across key parameters including insertion and withdrawal, needle advancement and retraction, puncture, repeated use, and fluid delivery. Additionally, package integrity was verified through visual inspection, peel strength, dye penetration, and splitting resistance tests using a worst-case representative model. All test samples met predefined acceptance criteria, supporting the device’s stability and performance over its intended shelf life.

11. SUBSTANTIAL EQUIVALENCE

Based on the intended use, technological characteristics, performance testing, and comparison to the predicate device, the Single Use Injector NM-400/NM-401 needles raise no new issues of safety and effectiveness and are substantially equivalent to the predicate device Single Use Injector NM-600/610.

12. CONCLUSION

Based on the results of the comparison of the indications for use, technological characteristics, and performance testing of the Subject and Predicate devices, the Subject Single Use Injector NM-400/NM-401 needle raises no new issues of safety and effectiveness and the device is substantially equivalent to the Predicate device.