



July 29, 2025

Olympus Medical Systems Corporation
Jillian Connery
Program Manager Regulatory Affairs
2951 Ishikawa-cho
Hachioji-shi, Tokyo 192-8507
Japan

Re: K251664

Trade/Device Name: Single Use Aspiration Needle (NA-201SX-4021); Single Use Aspiration Needle
(NA-201SX-4022)

Regulation Number: 21 CFR 874.4680

Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories

Regulatory Class: Class II

Product Code: KTI

Dated: May 30, 2025

Received: May 30, 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,

John S. Bender -S
2025.07.29 09:06:53 -04'00'

for Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental 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.

K251664

?

Please provide the device trade name(s).

?

Single Use Aspiration Needle (NA-201SX-4021);
Single Use Aspiration Needle (NA-201SX-4022)

Please provide your Indications for Use below.

?

The Single Use Aspiration Needle NA-201SX-4021 is intended to be used for ultrasound guided fine needle aspiration (FNA) of submucosal and extramural lesions of the tracheobronchial tree in combination with an ultrasound endoscope.

The Single Use Aspiration Needle NA-201SX-4022 is intended to be used for ultrasound guided fine needle aspiration (FNA) of submucosal and extramural lesions of the tracheobronchial tree in combination with an ultrasound 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 ASPIRATION NEEDLES**510(k) SUMMARY****510(k) Summary: K251664****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
800 West Park Drive
Westborough, MA 01581
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: 25-July-2025**2. PRODUCT INFORMATION**

- Trade Name: Single Use Aspiration Needle
- Models: NA-201SX-4021, NA-201SX-4022
- Common Name: Aspiration Needle
- Classification Name: Bronchoscope (flexible or rigid) and accessories
- Product Code: KTI
- Regulation Number: 21 CFR 874.4680
- Regulation Name: Bronchoscope (flexible or rigid) and accessories
- Device Class: II

3. PREDICATE DEVICE

- Trade Name: Single Use Aspiration Needle
- Model: NA-U401SX-4025N
- 510(k) Number: K190239

4. REFERENCE DEVICE

- Trade Name: ViziShot 2 FLEX
- Model: NA-U403SX-4019
- 510(k) Number: K163469

5. DEVICE DESCRIPTION

The Olympus Single Use Aspiration Needle NA-201SX-4021 and NA-201SX-4022 are designed for use with ultrasound endoscopes for ultrasound-guided fine needle aspiration (FNA) of submucosal and extramural lesions of the tracheobronchial tree. These devices are single-use, disposable, sterile (Ethylene Oxide) needles available in two models with different specifications:

- NA-201SX-4021:
 - Working Length: 700mm
 - Maximum Insertion Portion Diameter: 1.9mm
 - Needle Width: 21G
 - Normal Needle Length: 20mm
 - Maximum Needle Length: 40mm
- NA-201SX-4022:
 - Working Length: 700mm
 - Maximum Insertion Portion Diameter: 1.8mm
 - Needle Width: 22G
 - Normal Needle Length: 20mm
 - Maximum Needle Length: 40mm

Both models feature an adjustable sheath length and are intended for single use.

6. INDICATIONS FOR USE

The Single Use Aspiration Needle NA-201SX-4021 is intended to be used with ultrasound endoscopes for ultrasound-guided fine needle aspiration (FNA) of submucosal and extramural lesions of the tracheobronchial tree.

The Single Use Aspiration Needle NA-201SX-4022 is intended to be used with ultrasound endoscopes for ultrasound-guided fine needle aspiration (FNA) of submucosal and extramural lesions of the tracheobronchial tree.

7. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The subject devices share the same intended use and technological characteristics as the predicate device, including design, materials, and operational features. Key similarities and differences are outlined below:

- **Similarities:**
 - Same product code, classification, regulation number, common name, regulation name, and review panel.
 - Same mechanism of tissue sampling (aspiration), ultrasound scanning direction, sheath composition, general design, syringe type, connector type, compatible endoscopes, method of sterilization, shelf life, energy used, visualization, and patient contact materials.
- **Differences:**
 - Needle width: NA-201SX-4021 (21G), NA-201SX-4022 (22G) vs. Predicate Device (25G).
 - Maximum insertion portion diameter: NA-201SX-4021 (1.9mm), NA-201SX-4022 (1.8mm) vs. Predicate Device (1.5mm).

Refer to Table 1 for Comparison of Technological Characteristics:

DESCRIPTION	SUBJECT DEVICE NA-201SX-4021 / NA-201SX-4022	PREDICATE DEVICE NA-U401SX-4025N (K190239)	COMPARISON
Product Code	KTI	KTI	Same
Classification	Class II	Class II	Same
Regulation Number	21 CFR 874.4680	21 CFR 874.4680	Same
Common Name	Aspiration Needle	Aspiration Needle	Same
Indications for Use	The Single Use Aspiration Needle NA-201SX-4021 is intended to be used for ultrasound guided fine needle aspiration (FNA) of submucosal and extramural lesions of the tracheobronchial tree in combination with an ultrasound endoscope.	This instrument has been designed to be used with ultrasound endoscopes for ultrasound guided fine needle aspiration (FNA) of submucosal and extramural lesions of the tracheobronchial tree.	Same

	The Single Use Aspiration Needle NA-201SX-4022 is intended to be used for ultrasound guided fine needle aspiration (FNA) of submucosal and extramural lesions of the tracheobronchial tree in combination with an ultrasound endoscope.		
Working Length	700 mm	700 mm	Same
Needle Gauge	21G (4021), 22G (4022)	25G	Different – verified through bench testing
Max Insertion Diameter	1.9 mm (4021), 1.8 mm (4022)	1.5 mm	Different – verified through bench testing
Needle Length (Normal/Max)	20 mm / 40 mm	20 mm / 40 mm	Same
Sheath Length	Adjustable	Adjustable	Same
Mechanism of Sampling	Aspiration	Aspiration	Same
Ultrasound Scanning Direction	Parallel to insertion	Parallel to insertion	Same
Compatible Endoscope Channel Diameter	Ø 2.2 mm	Ø 2.0–2.2 mm	Similar - Subject device is optimized for 2.2 mm channels only; performance equivalence to broader predicate compatibility was demonstrated through bench testing.
Compatible Endoscope Working Length	600 mm / BF	600 mm / BF	Same
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same
Shelf Life	3 years	3 years	Same
Single Use / Reusable	Single Use	Single Use	Same
Connector Type	Luer lock	Luer lock	Same
Patient Contact Materials	SUS304, NiTi, PTFE	SUS304, NiTi, PTFE	Same
Visualization	Ultrasound-guided	Ultrasound-guided	Same

8. PERFORMANCE DATA

Performance testing was conducted to demonstrate the safety and effectiveness of the Single Use Aspiration Needle NA-201SX-4021 and NA-201SX-4022. The following tests were performed and passed the acceptance criteria:

- Insertion performance into the endoscope – all results met acceptance criteria for smooth insertion and effective tissue penetration
- Piercing performance of the needle - all results met acceptance criteria for effective tissue penetration
- Ultrasound visibility of the needle – all results met acceptance criteria for visibility of the needle under ultrasound imaging.
- Needle extraction and retraction performance - The device met all predefined criteria for safe and effective needle extraction and retraction
- Needle aspiration performance- The device successfully aspirated target material under test conditions
- Withdrawal performance from the endoscope - The needle was withdrawn smoothly and safely from the endoscope
- Needle slider performance - The slider mechanism functioned reliably for needle deployment and retraction
- Limitation of needle depth - The device effectively limited needle extension to within specified parameters
- Needle-to-luer joint pull strength - The joint withstood required tensile forces without failure
- Sheath-to-handle joint pull strength - The connection between sheath and handle remained secure under stress
- Needle breakage strength - The needle demonstrated sufficient structural integrity under load
- Coil separation - The coil remained intact and did not separate under test conditions

9. BIOCOMPATIBILITY

Biocompatibility testing was conducted in accordance with ISO 10993-1 and relevant FDA guidance. The NA-201SX series was evaluated for cytotoxicity, sensitization, irritation, acute systemic toxicity, material-mediated pyrogenicity, hemocompatibility, and aged cytotoxicity. All tests met acceptance criteria, confirming that the device is biologically safe and biocompatible for its intended use. These results demonstrate that the subject device does not introduce new biocompatibility risks and supports a determination of substantial equivalence to the predicate device.

10. STERILIZATION AND SHELF LIFE

Sterilization testing confirmed that the NA-201SX-4021 and NA-201SX-4022 devices meet endotoxin limits and achieve a sterility assurance level of 10^{-6} using ethylene oxide. Shelf-life testing validated a three-year shelf life through accelerated aging and simulated distribution, with all packaging integrity and product performance tests passing acceptance criteria. These results support the device's continued safety and substantial equivalence to the predicate device.

11. SUBSTANTIAL EQUIVALENCE

Based on the intended use, technological characteristics, performance testing, and comparison to the predicate device, the Olympus Single Use Aspiration Needles NA-201SX-4021 and NA-201SX-4022 are substantially equivalent to the predicate device NA-U401SX-4025N.

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 Olympus SINGLE USE ASPIRATION NEEDLES device is substantially equivalent to the Predicate device NA-U401SX-4025N.