October 24, 2025

Olympus Medical Systems Corp.
℅ Jillian Connery
Program Manager RA
Olympus Corporation of the Americas
800 West Park Drive
Westborough, Massachusetts 01581

Re: K252646
Trade/Device Name: Single-Use Fine Needle Biopsy (FNB) device (NA-U210H)
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: FCG
Dated: August 15, 2025
Received: August 21, 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,

SIVAKAMI VENKATACHALAM -S

for
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.	K252646

Please provide the device trade name(s).

Single-Use Fine Needle Biopsy (FNB) device (NA-U210H)

Please provide your Indications for Use below.

The Single-use Fine Needle Biopsy (FNB) device NA-U210H has been designed to be used with an ultrasound endoscope for sampling of submucosal and extramural lesions within or adjacent the gastrointestinal tract.

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 FINE NEEDLE BIOPSY (FNB)

510(k) SUMMARY

510(k) Summary: K252646

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
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• Manufacturing Site
AOMORI OLYMPUS CO., LTD.
2-248-1 OKKONOKI
KUROISHI_SHI Aomori, Japan
FDA Establishment Registration #: 3003995201

• **Date Prepared:** 21-Aug-2025

2. PRODUCT INFORMATION

- Trade Name: Single-Use Fine Needle Biopsy
- Models: NA-U210H
- Common Name: Fine Needle Biopsy
- Classification Name: Gastroenterology-Urology Biopsy Instrument
- Product Code: FCG
- Regulation Number: 21 CFR 876.1075
- Regulation Name: Gastroenterology-Urology Biopsy Instrument
- Device Class: II

3. PREDICATE DEVICE

- Trade Name: Single-use Aspiration Needle
- Model: NA-U200H
- 510(k) Number: K180449

4. DEVICE DESCRIPTION

The Single-Use Fine Needle Biopsy (FNB) Device NA-U210H (SecureFlex) is a sterile, single-use fine needle biopsy device intended for use with an ultrasound endoscope to sample submucosal and extramural lesions within or adjacent to the gastrointestinal tract. It consists of:

- **Biopsy Needle Assembly**: Handle, needle (19G, 22G, or 25G), and coiled sheath.
- **Aspiration System**: VACLOK syringe and stopcock (FDA-cleared under K994253).

The device features a bifurcated needle tip for enhanced tissue acquisition, echo-enhanced regions for ultrasound visibility, and is compatible with Olympus GF and TGF endoscopes with ≥2.8 mm channel diameter.

5. INDICATIONS FOR USE/INTENDED USE

The Single-Use Fine Needle Biopsy (FNB) Device NA-U210H has been designed to be used with an ultrasound endoscope for sampling of submucosal and extramural lesions within or adjacent to the gastrointestinal tract.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The Single-Use Fine Needle Biopsy (FNB) Device NA-U210H 0H is substantially equivalent to the NA-U200H (K180449) in terms of:

- Intended use
- Technological characteristics
- Materials
- Sterilization method (EO)
- Biocompatibility
- Performance

Differences include:

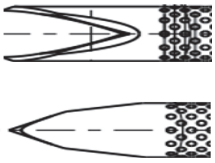
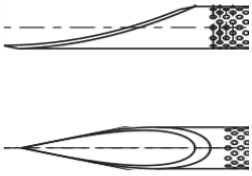
- Bifurcated needle tip (vs. single tip)
- No side hole (simplified design)
- Minor internal handle design changes for improved assembly

These differences do not raise new questions of safety or effectiveness.

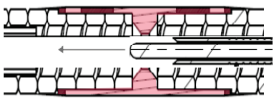
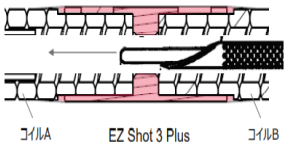
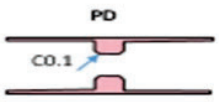
Refer to Table 1 for Comparison of Technological Characteristics:

Feature	Subject Device	Predicate Device	Comparison
Model	SINGLE-USE FINE NEEDLE BIOPSY (FNB) DEVICE NA-U210H	SINGLE-USE ASPIRATION NEEDLE NA-U200H	The model name and number are changed to identify the new device.
Company	OLYMPUS MEDICAL SYSTEMS CORP.	OLYMPUS MEDICAL SYSTEMS CORP.	Same
510(k) Number	-	K180449	K180449 listing is for reference.
Indications for use	The Single-use Fine Needle Biopsy (FNB) NA-U210H device has been designed to be used with an ultrasound endoscope for sampling of submucosal and extramural lesions within or adjacent the gastrointestinal tract.	This instrument has been designed to be used with Olympus ultrasound endoscope for ultrasound guided fine needle aspiration (FNA) and fine needle biopsy (FNB) of submucosal and extramural lesions within the gastrointestinal tract (i.e. pancreatic masses, mediastinal masses, perirectal masses and lymph nodes)	The Subject Device Indications for Use is the same as the predicate. The examples were removed from the Subject Device Indications for Use.
Regulation name	Gastroenterology-Urology Biopsy Instrument	Gastroenterology-Urology Biopsy Instrument	Same
Regulation number	876.1075	876.1075	Same
Regulatory Class	II	II	Same
Product Code	FCG	FCG	Same
Classification	Gastroenterology and	Gastroenterology and	Same

Feature	Subject Device	Predicate Device	Comparison
Panel	Urology	Urology	
Compatible Ultrasound endoscope	Model & Working length: GF/ 1250mm TGF/ 1245mm Channel inner diameter: 2.8 mm or more	Model & Working length: GF/ 1244 to 1265mm TGF/ 1245mm Channel inner diameter: 2.8 mm or more	Same
Needle Width	NA-U210H-8019: 19G NA-U210H-8022: 22G NA-U210H-8025: 25G	NA-U200H-8019, NA-U200H-8019S: 19G NA-U200H-8022, NA-U200H-8022S: 22G NA-U200H-8025: 25G	Same
Penetration Depth	80mm	80mm	Same
Maximum insertion portion diameter	NA-U210H-8019:2.6mm NA-U210H-8022:2.2mm NA-U210H-8025:2.2mm	NA-U200H-8019, NA-U200H-8019S:2.6mm NA-U200H-8022, NA-U200H-8022S:2.2mm NA-U200H-8025:2.2mm	Same
Working length	1400mm Working length indicates the same length as when the sheath adjuster is positioned at sheath scale 3.	1400mm Working length indicates the same length as when the sheath adjuster is positioned at sheath scale 3.	Same
Sheath Type	Coiled Sheath	Coiled Sheath	Same
Inner Sheath	Equipped	Equipped	Same
Joining of Sheath	Equipped	Equipped	Same
Stylet diameter	NA-U210H-8019:0.75mm NA-U210H-8022:0.41mm	NA-U200H-8019, NA-U200H-8019S:0.75mm NA-U200H-8022, NA-U200H-8022S:0.41mm	Same

Feature	Subject Device	Predicate Device	Comparison
	NA-U210H-8025:0.28mm	NA-U200H-8025:0.28mm	
Side Hole of Needle	Not equipped	NA-U200H-8019S, NA-U200H-8022S:Equipped NA-U200H-8019, NA-U200H-8022:Not equipped NA-U200H-8025: Not equipped	The subject device does not include a side hole feature, which simplifies the product configuration. This design choice enhances needle durability and does not introduce any new concerns regarding safety or effectiveness.
Joining of Needle	Equipped	Equipped	Same
Tip Shape of Needle			Different than Predicate device The needle tip shape of the Single-Use Fine Needle Biopsy (FNB) Device NA-U210H differs from the predicate device, featuring a bifurcated design intended to enhance tissue collection by allowing larger sample volumes. Despite this design change, needle durability

Feature	Subject Device	Predicate Device	Comparison
			remains equivalent to the predicate, as demonstrated in performance testing (refer to K-PERB_001). This difference does not impact the device's safety or effectiveness.
Echo Enhanced Region	Equipped	Equipped	Same
Elastomer on Handle	Equipped	Equipped	Same
Needle Stopper	Equipped	Equipped	Same
Sheath Slide Function	Equipped	Equipped	Same
Knob Dropout Prevention	Equipped	Equipped	Same
Syringe (for aspiration)	Equipped	Equipped	Same
Biocompatibility	Meets requirements	Meets requirements	Same
Sterilization Method	EO, Single-use	EO, Single-use	Same
Shelf Life	Three years	Three years	Same

Feature	Subject Device	Predicate Device	Comparison
Handle design change			There is no difference in specification between the subject device and predicate device, only the content printed on the handle is changed. Changes in the printing on the subject device handle make it possible to distinguish it easily from existing products and emphasize the uniqueness of the new product. This difference does not raise any concern on safety and effectiveness.
Dimensional changes to inner components of the handle	 EZ Shot 4 	 EZ Shot 3 Plus 	Different than Predicate device Since the needle is bifurcated for the subject device, the needle tip can easily come into contact with the parts during assembly, so the inner surface shape has been changed for the purpose of improving the ease of assembly.

OLYMPUS

Feature	Subject Device	Predicate Device	Comparison
			The size of the C chamber will be changed from 0.1mm to 0.5mm (the weight will be slightly reduced). There is no change in the material, processing destination, and processing method (cutting) of the parts when compared to the Predicate device. Hence, the difference does not affect the safety and effectiveness of the subject device.
Sheath	Stainless steel	Stainless steel	Same
Needle	NA-U210H-8019, NA-U210H-8022:Nitinol & Stainless steel(SUS 304TP) * The Nitinol needle is joined to the SUS needle NA-U210H-8025: Stainless steel (SUS 304)	NA-U200H-8019S, NA-U200H-8022S, NA-U200H-8019, NA-U200H-8022:Nitinol & Stainless steel(SUS 304TP) * The Nitinol needle is joined to the SUS needle NA-U200H-8025: Stainless steel (SUS 304)	Same
Stylet	Nitinol	Nitinol	Same

Feature	Subject Device	Predicate Device	Comparison
Distal tip	Stainless steel	Stainless steel	Same
Inner Sheath	PEEK&HDPE	PEEK&HDPE	Same

7. PERFORMANCE DATA

Bench performance testing was conducted on all gauge sizes (19G, 22G, 25G) of the Single-Use Fine Needle Biopsy (FNB) Device NA-U210H device using 30 samples per model. The following tests were performed:

- Insertion into the endoscope
- Advancement of the needle
- Retraction of the stylet
- Visibility of the needle under ultrasound
- Aspiration using the syringe
- Retraction of the needle
- Withdrawal from the endoscope
- Specimen extraction by feeding air
- Specimen extraction by advancing the stylet
- Repetition test (7 cycles)
- Needle durability
- Animal study – tissue quantity and quality

All test items met predefined acceptance criteria, confirming the device's mechanical performance, usability, and durability under simulated worst-case conditions.

8. BIOCOMPATIBILITY

The Single-use Fine Needle Biopsy (FNB) Device NA-U210H was evaluated for biocompatibility in accordance with ISO 10993-1:2018 and FDA guidance for external communicating devices with tissue contact for limited duration (≤24 hours). Testing was conducted using the biologically equivalent predicate device NA-U200H, which shares materials, sterilization method, and manufacturing processes. The following endpoints were assessed: cytotoxicity (initial and aged samples), sensitization, irritation/intracutaneous reactivity, acute systemic toxicity, material-mediated pyrogenicity, hemocompatibility, and bacterial-mediated pyrogenicity. All tests met acceptance criteria, confirming the biological safety of the device for its intended use.

9. STERILIZATION AND SHELF LIFE

The Single-Use Fine Needle Biopsy (FNB) Device NA-U210H is sterilized using ethylene oxide (EO), with validation conducted to ensure appropriate sterility assurance levels for single-use medical devices. Shelf life is supported by comprehensive testing, including accelerated aging per ASTM F1980-21, ongoing real-time aging, simulated distribution testing, and packaging system stability per ISO 11607-1:2019 and ISO 11607-2:2019. Functional performance testing on aged devices confirmed that sterility, mechanical integrity, and packaging remained intact over a validated shelf life of three years.

10. SUBSTANTIAL EQUIVALENCE

Based on the intended use, technological characteristics, performance testing, and comparison to the predicate device, the Single-Use Fine Needle Biopsy (FNB) Device NA-U210H raises no new issues of safety and effectiveness and are substantially equivalent to the predicate device.

11. 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 FINE NEEDLE BIOPSY (FNB) DEVICE NA-U210H raises no new issues of safety and effectiveness and the device is substantially equivalent to the Predicate device.