June 5, 2025

Grumpy Innovation, Inc.
Billi-Jo Pfalzgraf
Regulatory Consultant
2601 S Minnesota Ave
Ste 105
Sioux Falls, South Dakota 57105-4750

Re: K243639
Trade/Device Name: Portare System (FA-001)
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOB
Dated: May 7, 2025
Received: May 7, 2025

Dear Billi-Jo Pfalzgraf:

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,

Joyce C. Lin -S

for Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243639

Device Name

PORTARE System (FA-001)

Indications for Use *(Describe)*

The Grumpy Innovation PORTARE System is intended for endoscopic procedures and examination within the nasal lumens and upper airway anatomy. The endoscope is intended to provide visualization via a monitor. The endoscope is intended for use in a hospital or clinical environment. It is intended for use in adults.

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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The 510(k) Summary

K243639

Date Summary Prepared:	May 07, 2025
Submitter:	Grumpy Innovation, Inc. 2601 S Minnesota Ave STE 105 Sioux Falls, SD 57105
Contact Person:	Billi-Jo Pfalzgraf Regulatory Affairs MedEdge Consulting Phone: 707-799-6732 Email: bjpfalzgraf@mededge.io
Device Trade Name:	PORTARE System
Device Common Name:	Flexible Nasopharyngoscope System
Device Classification:	Nasopharyngoscope (flexible or rigid) Product Code: EOB 21 CFR 874.4760 Class II Review Panel: Ear, Nose, & Throat
Legally marketed devices to which the device is substantially equivalent:	Predicate Device: K181286 Ambu aScope RLS Slim Reference Device: K200609 ENTity WiFi Video Nasopharyngoscope System
Description of Device:	The Grumpy Innovation PORTARE System is a flexible endoscope with steerable navigation and a built-in image and video processing system that wirelessly transmits images and video to a tablet application. The PORTARE System is comprised of a: • Sterile, single-use disposable endoscope handle, steering mechanism, and steerable insertion tube with chip-on-tip camera and LED light source. • Reusable module comprising the primary circuit board with wireless unit and rechargeable battery. • Tablet viewer that runs a software application. The reusable module attaches to the single-use disposable endoscope handle to create a functional endoscope.
Indication for Use:	The Grumpy Innovation PORTARE System is intended for endoscopic procedures and examination within the nasal lumens

	and upper airway anatomy. The endoscope is intended to provide visualization via a monitor. The endoscope is intended for use in a hospital or clinical environment. It is intended for use in adults.
Summary of the technological characteristics in comparison to the predicate device:	The Grumpy Innovation PORTARE System is similar to the predicate device in the following ways: • They both have the same intended use, indication for use, and similar use environment. • They both have a sterile, single-use component that connects with a reusable component to illuminate and visualize. • They both have the same direction of view, articulation angle, and lack of working channel. • They both employ a chip-on-tip camera and LED light source located at the distal tip. • They both have the same method of terminal sterilization. • The PORTARE is similar to the reference device for latency. Technical characteristics of the PORTARE System differ from the predicate in the following areas: • Field of View • Depth of field • Insertion tube diameter • Insertion tube length • Wireless transmission • Power Source • Reprocessing Method Performance and safety testing demonstrated that these technological differences do not raise any new questions of safety and effectiveness of the subject device.
Performance Tests (Non-Clinical):	The following performance data were provided in support of the substantial equivalence determination: Performance test reports to document the following properties of the PORTARE System: • Dimensional/Physical Inspection • Module Engagement/Disengagement • Module Lifecycle Connection Characterization • Mechanical Durability • ISO 8600: ISO 8600-1, ISO 8600-3, ISO 8600-4 • Optical Performance ISO 12233, ISO 15739 • Deflection Control System • Latency Testing (compared to reference device) • Summative Usability in accordance with IEC 62366-1 Result: All tests were passed.

Performance test reports to document shelf life of PORTARE System WireCam. Tests were performed on finished, sterilized and aged products:

- Sterilization Validation ISO 11135
- Ethylene Oxide Residuals ISO 10993-7
- Sterile Package Integrity ISO 11607-1, ASTM D4169-22, ASTM F1886/F1886M-16, ASTM F88/F88M-23, ASTM F2096-11, ASTM F1980-21
- Performance testing of PORTARE WireCam

Result: All tests were passed.

Performance test reports to document validated reprocessing methods of the PORTARE Module:

- Cleaning Validation in accordance with ANSI/AAMI ST98 and AAMI TIR12
- Intermediate Level Disinfection in accordance with ANSI/AAMI ST98 and AAMI TIR12

Result: All tests were passed.

Biocompatibility test reports to document that the PORTARE System complies with the requirements of ISO 10993-1:

- Cytotoxicity ISO 10993-5
- Intracutaneous Irritation ISO 10993-23
- Sensitization ISO 10993-10

Result: All tests were passed.

Performance test reports to document Software verification and Cybersecurity testing of the PORTARE System:

- Software verification testing was performed as recommended by FDA Guidance, “Content of Premarket Submissions for Device Software Functions”
- Cybersecurity testing was performed as recommended by FDA Guidance, “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions”

Result: All tests were passed.

Test reports that verify the Electrical Safety and Electromagnetic Compatibility of the PORTARE System:

- Electrical Safety in accordance with IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-18
- Battery Safety testing in accordance with IEC 62133-2
- Photobiological Safety in accordance with IEC 62471
- Electromagnetic Compatibility in compliance with IEC 60601-1-2
- Radio Frequency Safety Testing in accordance with ANSI C63.10
- Wireless Coexistence testing in accordance with ANSI C63.27 and in simulated high intensity environment

Result: All tests were passed.

Performance Data – Clinical:	Not applicable
Substantial Equivalence:	Based on the Indication for Use, design, safety, and performance testing, the Grumpy Innovation PORTARE System met the requirements for its intended use and is substantially equivalent to the predicate device.
Conclusion:	The results of all testing demonstrate that the Grumpy Innovation PORTARE System is substantially equivalent to the predicate device.