September 6, 2024

Alandra Medical SAPI de CV
% Randy Prebula
Partner
Hogan Lovells US LLP
555 Thirteenth Street, NW
Washington, District of Columbia 20004

Re: K233974
Trade/Device Name: Mucosal Impedance Measurement System
Regulation Number: 21 CFR 876.1450
Regulation Name: Esophageal Tissue Characterization System
Regulatory Class: Class II
Product Code: QIS, PIF
Dated: August 6, 2024
Received: August 6, 2024

Dear Randy Prebula:

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.

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,
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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)*

K233974

Device Name

Mucosal Impedance Measurement System

Indications for Use *(Describe)*

The Mucosal Impedance Measurement System is indicated for use by medical personnel trained in the usage of enteral feeding tubes for the treatment of adult patients requiring gastric decompression or enteral feeding for the delivery nutrition, fluids, and medications to the patient from an enteral feeding syringe or feedings set designed with ENFit connectors. The measurements of the Mucosal Impedance Measurement System are collected in patients indicated for enteral feeding. This product is single use for no longer than 24 hours.

The Mucosal Impedance Measurement System is equipped with sensors designed to collect and display real time and continuous gastric reactance "XL" measurements. The device is not for use as a sole diagnostic screening tool and is restricted to prescription use in a hospital environment.

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.

510(k) SUMMARY

Alandra's Mucosal Impedance Measurement System

Submitter

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Mexico

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Contact Person: Montserrat Godinez Garcia

Date Prepared: August 6, 2024

Name of Device: Mucosal Impedance Measurement System

Classification Name: 876.1450 - Esophageal tissue characterization system

Regulatory Class: Class II

Product Code: QIS, PIF

Predicate Devices

Mucosal Integrity Conductivity (MI) Test System (DEN180067)

Nasogastric Feeding Tubes – ENFit Port – PVC (K213258)

Reference Devices

Entarik Feeding Tube (K230206)

Device Description

The Mucosal Impedance Measurement System senses passive electrical features of the gastric tissue that corelate to of epithelial integrity through a technique known as 'bioimpedance spectroscopy'. Bioimpedance spectroscopy measures the ability of tissue to conduct electricity (resistance) and the ability of tissue to store charged particles (reactance).

The Florence monitor model ISMO 1.0 is an electronic device that delivers electrical current to a small region of the gastric tissue through the Athena Catheter; the device measures the resultant voltage, and then calculates and displays impedance information in numeric and graphic representations. More specifically, to measure the bioimpedance of the gastric mucosa impedance, the device delivers electric current through the Athena Catheter. The resulting voltage developed between the two inner electrodes is sensed, filtered, amplified,

and then digitized by the electronic circuits of the monitor. Once the measured voltage from the gastric tissue has been digitized, a proprietary algorithm processes the information and calculates the impedance spectrum and the Central Reactance parameter (XL). The device displays the information as either a function of frequency or as a function of time.

Intended Use / Indications for Use

The Mucosal Impedance Measurement System is indicated for use by medical personnel trained in the usage of enteral feeding tubes for the treatment of adult patients requiring gastric decompression or enteral feeding for the delivery nutrition, fluids, and medications to the patient from an enteral feeding syringe or feedings set designed with ENFit connectors. The measurements of the Mucosal Impedance Measurement System are collected in patients indicated for enteral feeding. This product is single use for no longer than 24 hours.

The Mucosal Impedance Measurement System is equipped with sensors designed to collect and display real time and continuous gastric reactance “XL” measurements. The device is not for use as a sole diagnostic screening tool and is restricted to prescription use in a hospital environment.

The proposed indications differ from the predicate Mucosal Integrity Conductivity Test System (DEN180067) in that the predicate collects real time epithelial impedance measurements during endoscopy, whereas the Mucosal Impedance Measurement System collects impedance during nasogastric intubation. Additionally, the Mucosal Impedance Measurement System specifically outputs gastric reactance “XL” measurements. This difference does not alter the intended therapeutic use of the device as a tool for collecting impedance measurements in the upper gastric tract. When used as labeled, the impedance measurements for both the predicate and the Mucosal Impedance Measurement System are not for use as a sole diagnostic screening tool.

The enteral feeding part of the subject device’s indications for use is similar to that for the Nasogastric Feeding Tubes predicate device (K213258). The inclusion of feeding tube functionality does not alter the safety profile of the device, as the risks for the proposed device remain as outlined in DEN180067 which are supported by the same mitigation measures.

Furthermore, FDA has previously accepted the use of impedance sensors integrated into nasogastric tubes in the 510(k) cleared Entarik Feeding Tube (K230206). Although the indicated use of the impedance measurement in the Enatrik Feeding Tube is for confirming proper placement of the tube, the clearance demonstrates the suitability for evaluating the integration of impedance measurement technology into gastrointestinal tube and accessory devices.

Summary of Technological Characteristics

Impedance measurement of tissues in the upper gastric tract is the primary technological principle for both the subject and predicate Mucosal Integrity Conductivity (MI) Test System. Both the subject device and the predicate Nasogastric Feeding Tubes – ENFit Port – PVC (K213258) share the same technological principles to support enteral feeding and gastric

decompression. The proposed device functions by collecting and processing gastric impedance measurements using impedance measurement hardware integrated into the distal end of a gastric feeding tube. At a high level, the subject and predicate devices are based on the following same technological elements:

- Impedance collection hardware
- Signal processing software
- Impedance based user output
- Consist of single use and reusable components
- Similar tube lengths and French sizes
- Both tubes have markings and are radiopaque.

The following technological differences exist between the subject and predicate devices:

- Integration of impedance measurement hardware for the subject device into an enteral feeding tube rather than endoscopic placement.

- The proposed device is only for use in adult patients in a hospital environment

Performance Data - Summary of non-clinical bench studies

Non-clinical/bench studies conducted on the Mucosal Impedance Measurement System to demonstrate the safety and effectiveness of the device include Sterilization Validation, Packaging Validation, Shelf Life testing, Biocompatibility testing per ISO 10993-1, Software Verification and Validation, Electrical Safety and EMC testing, Performance testing for tensile properties, security of connectors, flow rate, and liquid leakage. The EnFit feeding connector of the Athena Catheter was tested per ISO 80369-3.

In all instances, the Mucosal Impedance Measurement System functioned as intended.

Test	**Methods**
Flow rate	"Gravity Flow Rate Testing in Enteral Tubes" as described in the "Catalog of Regulatory Science Tools to Help Assess New Medical Devices"
Tensile strength	EN1615:2000 Enteral Feeding Catheters And Enteral Giving Sets For Single Use And Their Connectors. Design And Testing (Section 4.1.1) EN1618:1997 Catheters other than intravascular catheters - Test methods for common properties (Annex B)
Liquid leakage	EN1615:2000 Enteral Feeding Catheters And Enteral Giving Sets For Single Use And Their Connectors. Design And Testing (Sections 4.1.3) EN1618:1997 Catheters other than intravascular catheters - Test methods for common properties (Annex C)

Security of connectors	EN1615:2000 Enteral Feeding Catheters And Enteral Giving Sets For Single Use And Their Connectors. Design And Testing (Sections 4.3.1) EN1618:1997 Catheters other than intravascular catheters - Test methods for common properties (Annex F)
Flexibility	ASTM F3505-21 Standard Test Method for Stent and Endovascular Prosthesis Kink Resistance
EnFit connector (dimensional verification, rigidity, fluid leakage test, stress cracking, resistance to separation from axial load, resistance to separation from unscrewing, resistance to overriding, and disconnection by unscrewing)	ISO 80369-3:2016 Small-bore connectors for liquids and gases in healthcare applications Part 3: Connectors for enteral applications
Sterilization validation	ISO 11135:2014 Sterilization of health-care products Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
Packaging validation	ISO 11607-1:2019 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
Dimensional verification	Overall length, working length, catheter outer diameter, catheter inner diameter, sensor dimensions, and spacing of the sensors
Accuracy - thermal stability	Thermal stability of the sensors has been verified by confirming that the measurements of the central reactance parameter (XL) remain consistent across a temperature range that covers the range 77-111°F (25-44°C). Stability of the sensors was confirmed in terms of the dispersion (standard deviation / interquartile range) of a statistically significative number of measurements across the temperature range. The PASS criterion was defined as confirming that at least 95% of all measurements are contained within a +/-1Ω tolerance.
Accuracy - temporal stability	Temporal stability of the sensors was verified by confirming that the measurements of the central reactance parameter (XL) remain consistent across 24 hours. Stability of the sensors was confirmed in terms of the dispersion (standard deviation / interquartile range) of a statistically significative number of measurements over the 24

	period. The PASS criterion was defined as confirming that at least 95% of all measurements are contained within a +/-1Ω tolerance (which corresponds to the accuracy stated in the Instructions for Use).

Biocompatibility

The Mucosal Impedance Measurement System is classified as mucosal membrane contacting for repeat, prolonged contact during clinical use(< 24 hours). The Athena Catheter was evaluated according to the FDA guidance (2023) "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The following biocompatibility endpoints were assessed for the Athena Catheter:

- Toxicity
- Irritation
- Sensitization

Results support the biocompatibility of the Athena Catheter.

Software

A failure or flaw of the software functions of the Mucosal Impedance Measurement System does not present a hazardous situation with a probable risk of death or serious injury to a patient, user of the device, or others in the environment of use. Therefore, the required level of documentation identified under FDA Guidance document “Content of Premarket Submissions for Device Software Functions” is basic documentation.

Electrical Safety and Electromagnetic Compatibility

The test reports address the basic safety evaluation (which includes electrical safety testing) per the FDA consensus standard IEC-60601-1.2005, AMD1.2012. Additionally, EMC testing was conducted per IEC-60601-1-2.2014, and passed the applicable clauses. The results support the electrical safety and EMC of the device.

Human factors

The Florence monitor and the Athena catheter’s usability has been validated in an actual clinical environment to support the safety and effectiveness of the device for their intended users and environment. This process was completed in accordance with the principles outlined in the "Applying Human Factors and Usability Engineering to Medical Devices" guidance. All evaluations have been performed according to EN 60601-1-6:2010, AMD1:2013 Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability.

Animal Study

The company completed a GLP prospective, controlled animal trial was performed with two groups, control group (CG) N=5 and shock (MAP ≤ 48 mmHg) group (SG) N= 16. The target monitoring time per subject and group was five continuous impedance measurements; the mean monitoring time was 5.10 ± 0.49 (4.28 to 5.82) hours. There were no adverse events related to the test articles. The testing demonstrated gastric impedance measurements were performed safely and demonstrated XL measurement was an indirect and consistent marker of gastric mucosal perfusion in the subject animals, which shows significant and detectable changes before commonly used markers of global perfusion under hypovolemic shock conditions.

Conclusions

The Mucosal Impedance Measurement System is as safe and effective as the Mucosal Integrity Conductivity (MI) Test System (DEN180067) and Nasogastric Feeding Tubes – ENFit Port – PVC (K213258). The Mucosal Impedance Measurement System has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor differences in indications do not alter the intended therapeutic use of the device and do not affect its safety and effectiveness when used as labeled. In addition, the technological differences between the Mucosal Impedance Measurement System and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Mucosal Impedance Measurement System is as safe and effective as the predicate devices. Thus, the Mucosal Impedance Measurement System is substantially equivalent.