



December 23, 2019

Diversatek Healthcare Inc.
Laura Boll
Vice President - Quality and Regulatory Affairs
9150 Commerce Center Circle, Suite 500
Highlands Ranch, CO 80129

Re: DEN180067
Trade/Device Name: Mucosal Integrity Conductivity (MI) Test System
Regulation Number: 21 CFR 876.1450
Regulation Name: Esophageal tissue characterization system
Regulatory Class: II
Product Code: QIS
Dated: December 14, 2018
Received: December 20, 2018

Dear Laura Boll:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Mucosal Integrity Conductivity (MI) Test System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

The Mucosal Integrity Conductivity Test System is indicated for use by gastroenterologists, surgeons, and medically trained personnel during an endoscopy to obtain a real time measurement of esophageal epithelial impedance. The device is not for use as a sole diagnostic screening tool.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Mucosal Integrity Conductivity (MI) Test System, and substantially equivalent devices of this generic type, into Class II under the generic name esophageal tissue characterization system.

FDA identifies this generic type of device as:

Esophageal tissue characterization system. An esophageal tissue characterization system is a device intended for obtaining measurements of electrical properties within esophageal tissue.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On

December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On December 17, 2018, FDA received your De Novo requesting classification of the Mucosal Integrity Conductivity (MI) Test System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Mucosal Integrity Conductivity (MI) Test System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request FDA has determined that, for the previously stated indications for use, the Mucosal Integrity Conductivity (MI) Test System can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risks to Health	Mitigation Measures
Device malfunction related to: <ul style="list-style-type: none"> • Breaking • Fractures • Unintentional separation of components • Inaccurate reading • Failure to sense • Endoscope incompatibility 	Non-clinical performance testing Shelf life testing Software verification, validation, and hazard analysis Labeling
Adverse tissue reaction	Biocompatibility evaluation
Electrical shock and electrical interference from other devices	Electrical safety testing Electromagnetic compatibility (EMC) testing Labeling
Procedural risks (which may include procedures of endoscopy with sedation)	Labeling
Infection/cross-contamination	Reprocessing validation Labeling

In combination with the general controls of the FD&C Act, the esophageal tissue characterization system is subject to the following special controls:

- (1) All patient contacting components of the device must be demonstrated to be biocompatible.
- (2) Performance testing must demonstrate the device can accurately measure the designated electrical characteristics.

- (3) Mechanical safety testing must demonstrate that the device will withstand forces encountered during use.
- (4) Software verification, validation, and hazard analysis must be performed.
- (5) Electromagnetic compatibility and electrical safety, mechanical safety, and thermal safety of the device must be performed.
- (6) Performance data must validate the reprocessing instructions for any reusable components of the device.
- (7) Labeling must include:
 - (i) Specific instructions regarding the proper placement and use of the device;
 - (ii) Instructions for reprocessing of any reusable components; and
 - (iii) An expiration date for single use components.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the esophageal tissue characterization system they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug

Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Pramodh Kariyawasam at 301-348-1911.

Sincerely,

for

Benjamin R. Fisher, Ph.D.

Director

OHT3: Office of GastroRenal, ObGyn,

General Hospital and Urology Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health