April 25, 2023

Diversatek Healthcare
Jim Prinster
Senior Design and Development Engineer
9150 Commerce Center Circle, Suite 500
Highlands Ranch, CO 80129

Re: K230056
Trade/Device Name: MiVu™ Esophageal Endo Cap
Regulation Number: 21 CFR 876.1450
Regulation Name: Esophageal tissue characterization system
Regulatory Class: Class II
Product Code: QIS
Dated: March 27, 2023
Received: March 27, 2023

Dear Jim Prinster:

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 (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 located 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.

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

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 Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Shanil P. Haugen -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K230056

Device Name
MiVu™ Esophageal Endo Cap

Indications for Use *(Describe)*

The MiVu Mucosal Integrity Testing System is indicated for use by gastroenterologists, surgeons, and medical personnel trained in endoscopic procedures during an endoscopy to obtain real-time measurement of esophageal epithelial integrity as an adjunct for the evaluation of esophageal disorders. The device is not for use as a sole diagnostic screening tool.

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.

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Section 5

510(k) Summary

510(k) Summary

The 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807.92.

1. Submission Sponsor and Contact

Submitter's Name:	Diversatek Healthcare
Submitter's Address:	9150 Commerce Center Circle, Suite 500 Highlands Ranch, CO 80129
Establishment Registration No.:	2023374
Contact Person:	Jim Prinster Senior Design and Development Engineer
Telephone:	303-865-8028
Email:	jprinster@diversatek.com
Date Prepared:	January 6, 2023

2. Candidate Device Identification

Trade Device Name:	MiVu™ Esophageal Endo Cap
FDA Product Code	QIS
Classification Name:	Esophageal tissue characterization system
Classification Number:	21 CFR 876.1450
Regulatory Class:	II

3. Predicate Device Identification

Predicate De Novo No.:	DEN180067
Predicate Trade Name:	MiVu™ Balloon Probe
Predicate FDA Product Code:	QIS
Predicate FDA Classification Name:	Esophageal tissue characterization system
Predicate Regulation No.:	21 CFR 876.1450
Predicate Regulatory Class:	II

This predicate device has not been subject to a design-related recall.

No reference devices were used in this submission.

4. MiVu Mucosal Integrity Testing System (MiVu System) Technology Overview

The Diversatek Healthcare MiVu Esophageal Endo Cap is the candidate accessory device for use with the approved predicate Diversatek Healthcare's MiVu Mucosal Integrity Testing system (MiVu System). The MiVu Esophageal Endo Cap is a new patient-contacting

accessory that will be used in place of the MiVu Balloon Probe already approved as part of the MiVu System.

The operating principle of the MiVu System is based on the known changes in mucosal conductivity which occur in the epithelial cells of the esophagus relative to the health of the tissue. The dilation of the intercellular spaces varies depending on the tissue condition presented (as described in the De Novo submission for the MiVu System DEN180067) such as gastroesophageal reflux disease (GERD), non-GERD, and eosinophilic esophagitis (EoE). With these conditions, as the intercellular spacing increases due to cellular damage, hydrogen ions permeate the voids between the epithelial cells. As a result, the mucosa becomes detectably more conductive than normal tissue, and as such, an impedance measurement (the inverse of conductivity) drops with increasing mucosal damage. The MiVu System is able to detect and acquire these impedance measurements for display and analysis.

During a typical procedure, the MiVu System is used to obtain impedance measurements of the esophageal tissue at various locations of interest. This is currently accomplished using the MiVu Balloon Probe which has impedance sensors (see section 5 Predicate Device Description below) that are placed in contact with the patient's esophageal mucosa, and measurement readings are taken. From these measurements, the system can generate a probability of the tissue disease type (GERD, non-GERD, EoE) which is used by the physician as an input to the treatment plan for the patient.

5. Predicate Device Description

The predicate device is the MiVu Balloon Probe which is an accessory probe for use with the MiVu Mucosal Integrity Testing System (MiVu System). The MiVu Balloon Probe consists of a patient contacting, non-compliant balloon with two rows (only a single row is required) of ten (10) impedance sensors positioned on opposite sides of the balloon. A conduit contains flexible circuits which connects the individual impedance sensor pads on the balloon to the circuit board inside the connector housing. The connector is then attached to the remainder of the predicate MiVu System through the MiVu Cable. The MiVu System digitizes the impedance signals and passes the data to the PC-based Zvu software for display and analysis.

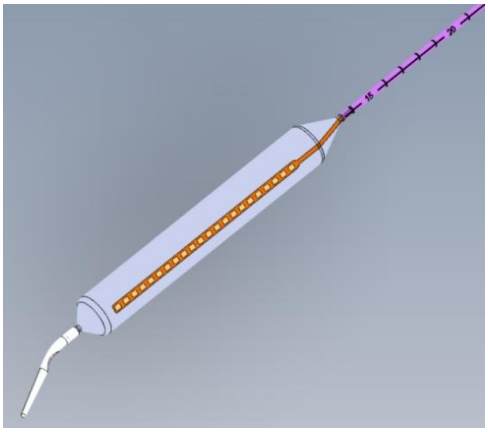

Figure 1 - MiVu Balloon Probe (predicate device)

The remainder of the MiVu System consists of the following components:

- PriZm Central Unit – digitizes impedance data and passes data to the PC-based Zvu software over a USB connection.
- MiVu Cable - connects the probe to the PriZm Central Unit.
- MiVu Regulator – facilitates inflation of the balloon probe. (This component is not used with the candidate device.)
- Zvu Software – acquires impedance data from the PriZm Central Unit, displays the data to facilitate analysis, applies an algorithm for determining disease probabilities, and generates a report which will be used as one of the inputs for developing the patient's treatment plan.
- PC and monitor

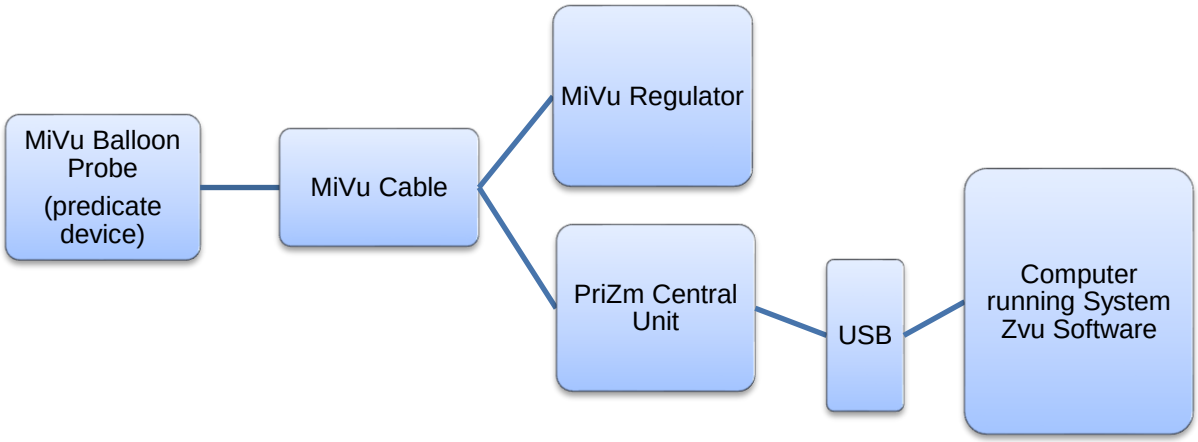

Figure 2 - MiVu System Components (predicate system)

A typical mucosal integrity study is performed at the conclusion of an endoscopic study. Once the endoscope is removed, the deflated MiVu Balloon Probe is intubated into the patient's esophagus and positioned just proximal to the patient's squamocolumnar junction (SCJ) based on the indexing measurements taken during the endoscopic study. The balloon is inflated using a syringe and the MiVu Regulator accessory. The impedance sensors that are along the sides of the balloon are pressed against the esophageal mucosa, a measurement reading is taken, and the balloon is deflated. The cycle of inflation-measurement-deflation is repeated several times to obtain a set of measurements the software will use to create a composite color-coded contour image of the impedance readings (see inset of Figure 3 and Figure 4). A study report may then be generated which is used as one of the inputs for developing the patient's treatment plan.

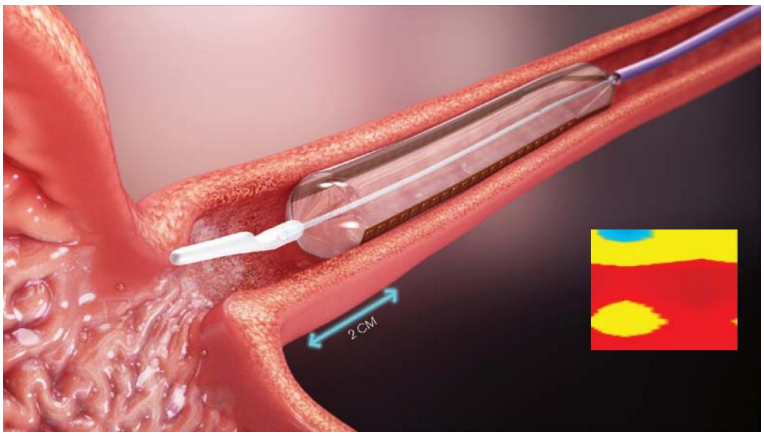

Figure 3 - Inflated MiVu Balloon Probe positioned in the esophagus

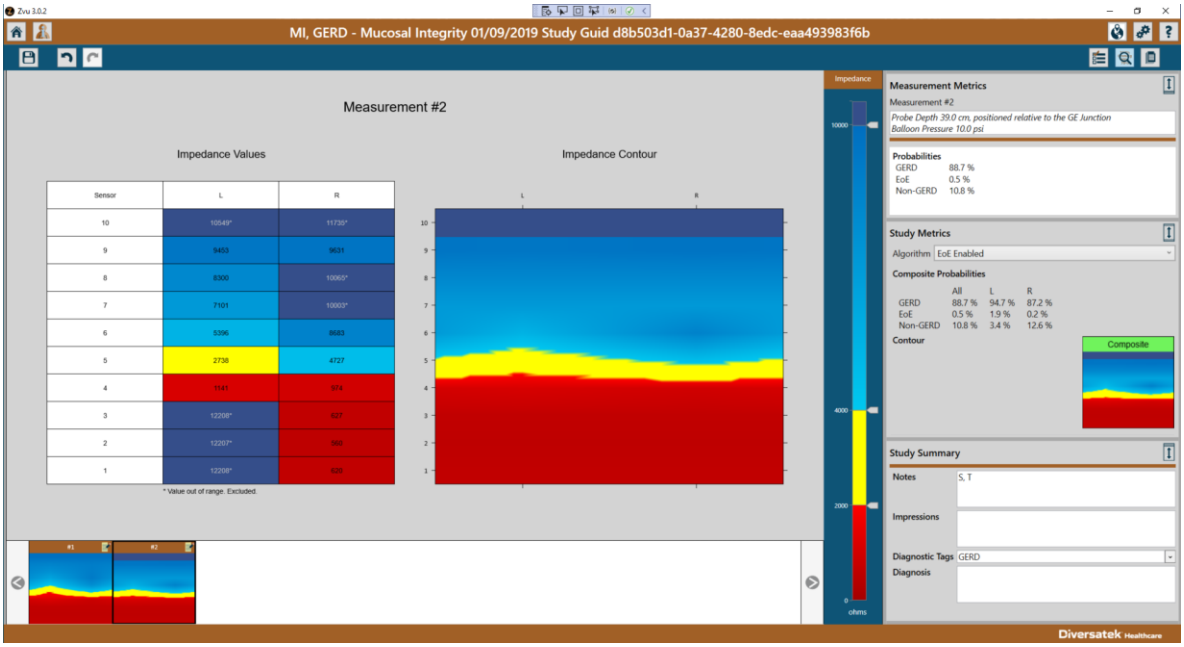

Figure 4 - Zvu Software MiVu study screen

6. Candidate Device Description

The candidate MiVu Esophageal Endo Cap device is intended to replace the predicate MiVu Balloon Probe when used with the MiVu System.

The MiVu Esophageal Endo Cap device consists of a patient contacting sensor tip that is installed over the working end of an endoscope. The tip is a flexible thermoplastic elastomeric tube with a single row of four (4) gold plated pads, providing three (3) impedance sensors evenly spaced along the length of the tip. The impedance sensors are

mounted on a pivoting platform to promote even contact of all sensor pads with the tissue. A polyurethane conduit tube containing interconnecting wires connects the individual impedance sensor pads on the sensor tip to the circuit board inside the connector housing. The connector is then attached to the remainder of the predicate MiVu System through the MiVu Endo Cap Cable. The MiVu System digitizes the impedance signals and passes the data to the PC-based Zvu software for display and analysis.

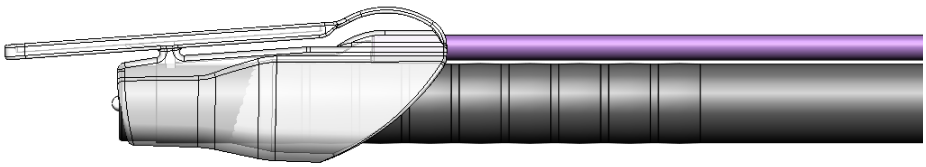

Figure 5 - MiVu Esophageal Endo Cap sensor tip on endoscope

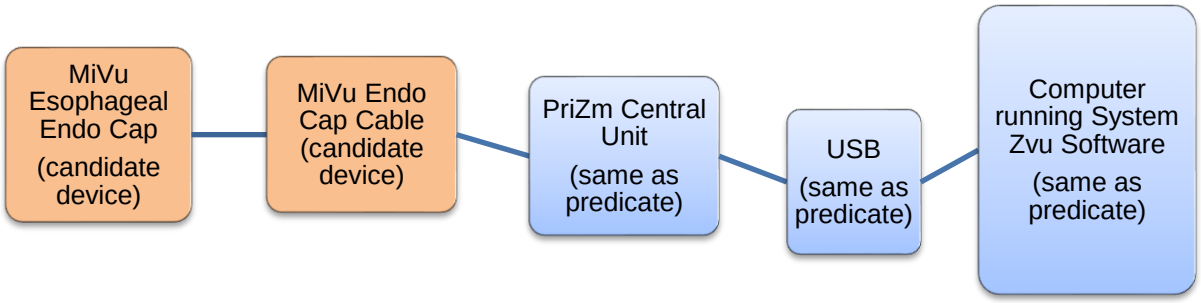

Figure 6 - MiVu System Components (candidate system)

In a typical study, the MiVu Esophageal Endo Cap is installed over the end of the endoscope prior to the intubation of the scope as shown in Figure 5 above. The tubular design of the tip allows for the lighting, optics and working channel of the endoscope to be used unimpeded. The sensor area of the device is denoted by a small protrusion that is visible with the endoscope camera to aid in locating the sensors against the esophageal tissue. When properly placed, the physician will rotate the tip of the scope into the sensors by turning the larger control wheel of the scope. This light pressure will cause the proximal end of the Endo Cap to pivot into the tissue, providing a constant pressure along the measurement region. Any luminal air or liquid between the sensors and mucosal tissue will be pressed away from the tissue being measured. During the endoscopic procedure, the physician will take multiple impedance readings of the epithelial layer spanning a minimum of 10 consecutive centimeters of the esophagus which the Zvu software will use to construct

a composite image. Once enough readings are obtained over 10 consecutive centimeters of the esophagus, the Zvu software will use the impedance values to calculate the disease probabilities for GERD (Gastro-Esophageal Reflux Disease), non-GERD and EoE (Eosinophilic Esophagitis) according to the algorithm used with the predicate balloon probe.

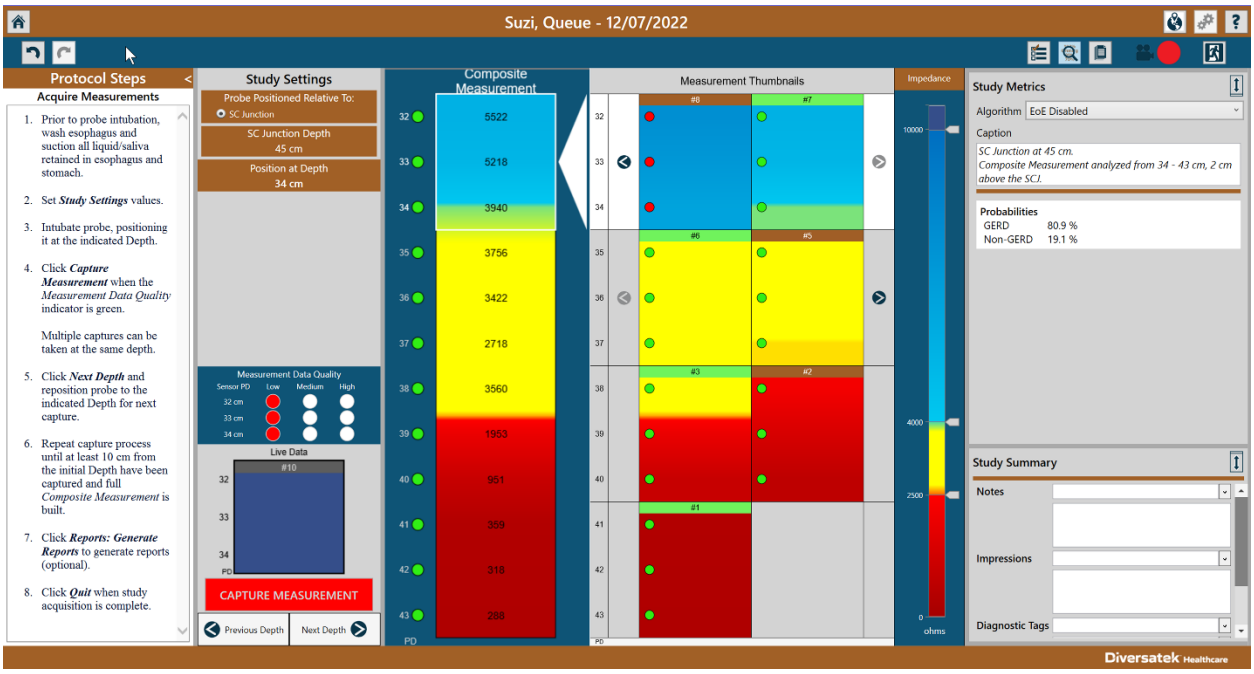

Figure 7 - Zvu Software MiVu Esophageal Endo Cap study acquisition screen

7. Intended Use

The MiVu Mucosal Integrity Testing System is intended to evaluate esophageal epithelial integrity to determine esophageal abnormalities by means of a device with direct electrical contact with the esophageal mucosal epithelium. The system includes associated signal conditioning hardware and software for measuring and displaying information.

8. Indications for Use

The MiVu Mucosal Integrity Testing System is indicated for use by gastroenterologists, surgeons, and medical personnel trained in endoscopic procedures during an endoscopy to obtain real-time measurement of esophageal epithelial integrity as an adjunct for the evaluation of esophageal disorders. The device is not for use as a sole diagnostic screening tool.

9. Technological Characteristics

The following table is a summary of the candidate MiVu Esophageal Endo Cap device technological characteristics as compared to the predicate MiVu Balloon Probe.

Table 1 - Summary of design, features and principles of operation

Characteristic	MiVu Esophageal Endo Cap (candidate device)	MiVu Balloon Probe (predicate device)	Comparison
De Novo/510(k) Number	TBD	DEN180067	N/A
FDA Product Code	QIS	QIS	Identical
FDA Classification Number	876.1450	876.1450	Identical
FDA Classification Name	Esophageal tissue characterization system	Esophageal tissue characterization system	Identical
Patient Contacting Materials	Tip: Thermoplastic Elastomer, Impedance Sensors: Gold-plated ENIG on a ceramic substrate, Outer Conduit Tube: Polyurethane Adhesive: Medical grade epoxy Conductor Covering Heat Shrink Tubing:	Tip: Polyurethane, Balloon: Polyethylene terephthalate (PET), Inflation Tube: Polyurethane tubing, Impedance Sensors: Gold-plated copper on a polyimide substrate, Outer Heat Shrink Tube: Polyether/Polyamide	Similar

Characteristic	MiVu Esophageal Endo Cap (candidate device)	MiVu Balloon Probe (predicate device)	Comparison
	Polyethylene terephthalate (PET)		
System Compatibility	MiVu Mucosal Integrity Testing System Reference: DEN180067	MiVu Mucosal Integrity Testing System Reference: DEN180067	Identical
Intended Use	The MiVu Mucosal Integrity Testing System is intended to evaluate esophageal epithelial integrity to determine esophageal abnormalities by means of a device with direct electrical contact with the esophageal mucosal epithelium. The system includes associated signal conditioning hardware and software for measuring and displaying information.	The MiVu™ Mucosal Integrity Testing System is intended to evaluate esophageal epithelial integrity to determine esophageal abnormalities by means of a balloon probe with direct electrical contact with the mucosal epithelium of the esophagus along with associated signal conditioning, hardware, and software for measuring and displaying information.	Similar
Indications for Use	The MiVu Mucosal Integrity Testing System is indicated for use by gastroenterologists, surgeons, and medical personnel trained in endoscopic procedures during an endoscopy to obtain real-time measurement of esophageal epithelial integrity as an adjunct for the evaluation of esophageal disorders. The device is not for use as a sole diagnostic screening tool.	The MiVu Mucosal Integrity Testing System is indicated for use by gastroenterologists, surgeons, and medically trained personnel during an endoscopy to obtain real-time measurement of esophageal epithelial integrity as an adjunct for the evaluation of esophageal disorders. The device is not for use as a sole diagnostic screening tool.	Similar
Environment	Professional Healthcare Office Environment, which includes hospitals, clinics, endoscopy suites, and clinical laboratories	Professional Healthcare Office Environment, which includes hospitals, clinics, endoscopy suites, and clinical laboratories	Identical

Characteristic	MiVu Esophageal Endo Cap (candidate device)	MiVu Balloon Probe (predicate device)	Comparison
Patient Population	Patients with suspected GI mucosal damage. Adult use only	Patients with suspected GI mucosal damage. Adult use only	Identical
Patient Contact Categorization	Gastrointestinal Tract	Gastrointestinal Tract	Identical
Configuration	Non-sterile single-use disposable device	Non-sterile single-use disposable device	Identical
Reusable Device	No	No	Identical
Shelf Life	6 months (initially)	6 months (initially)	Identical
Sensor Strips	1	2	Similar (see discussion below)
Sensors per strip	3	10	Similar (see discussion below)

Design Differences
The candidate MiVu Esophageal Endo Cap differs from the predicate MiVu Balloon Probe in the following features:

a) Sensor strips: The Endo Cap device utilizes only one strip of sensors while the predicate balloon probe utilizes two strips placed on opposite sides of the balloon. In a clinical study using the predicate MiVu Balloon Probe device, it was determined that only a single sensor strip was necessary to obtain data for a useful study. In a clinical study, it was found that the distinction of the MI patterns (GERD, non-GERD, and EoE) is presented along the esophageal axis, and radial measurements were not found to provide additional diagnostic utility.

10. Non-Clinical Performance Data

Diversatek Healthcare performed bench testing to support substantial equivalence. The following testing was performed on samples from initial production lots (where applicable):

a) Compatibility with the MiVu Mucosal Integrity Testing System
The MiVu Esophageal Endo Cap and MiVu Endo Cap Cable were tested to verify the accessory components were compatible with the MiVu Mucosal Integrity Testing System (MiVu System). Functional testing demonstrated the acquisition of impedance data and the authentication of the Endo Cap device.

b) Comparison to Predicate Function and Performance

The MiVu System utilizing the MiVu Esophageal Endo Cap was tested against the same MiVu System utilizing the predicate MiVu Balloon Probe device to demonstrate equivalence. This bench testing utilized a test medium that would allow for a true impedance reading (both AC and DC components such as measured with tissue) that was consistent across all sensors.

c) Biocompatibility
Biocompatibility testing was completed on the MiVu Esophageal Endo Cap per ISO 10993-1. This device complies with all applicable parts of the standard.

d) Electrical Safety and EMC
Electrical safety and EMC testing were conducted on the MiVu System utilizing a MiVu Esophageal Endo Cap and the MiVu Endo Cap Cable. This system configuration complies with the applicable requirements of IEC 60601-1:2005 (Ed 3) + Corr. 1:2006 + Corr. 2:2007 + A1:2012, IEC 60601-1-6:2010 (Third Edition) + A1:2013, and IEC 60601-1-2:2014 + Amd1:2020 (Ed 4.1).

e) Mechanical Safety Tests
The MiVu Esophageal Endo Cap device was subjected to tensile testing according to the test method described in ISO 10555-1:2013+A1:2017 Intravascular catheters – Sterile and single-use intravascular catheters – Part 1: General requirements, Annex B Method for determining peak tensile force.

The device was also subjected to a pull test of the retention of the device on a 9.9mm diameter endoscope.

f) Reprocessing of Non-single Use Components
The MiVu Esophageal Endo Cap device is a single-use disposable device, and as such, is not reprocessed.

The MiVu Endo Cap Cable is a reusable component of the MiVu System that has the potential for incidental contact with patient mucous when the soiled Endo Cap device is being disconnected and disposed. Because of this potential for incidental soiling, the MiVu Endo Cap Cable should be reprocessed after each use. The reprocessing instructions outlined in the MiVu System IFU for cleaning and low-level disinfection were validated by a third-party testing lab.

g) Bioburden and Shipping Simulation
The MiVu Esophageal Endo Cap device is a single-use disposable device. The devices are manufactured in a controlled environment that is regularly monitored for bioburden. The Endo Cap devices were tested for bioburden levels pre- and post- shipping simulation to verify the packaging effectiveness and verify the mechanical integrity of the packaging.

11. Software

The MiVu Mucosal Integrity Testing System (MiVu System) utilizes both embedded firmware and PC-based software. The embedded firmware runs on microprocessors in the PriZm

Central Unit and the MiVu Endo Cap Cable accessory component. The PC-based software, called Zvu, is used for the acquisition and analysis of clinical data for both the predicate device configuration and the candidate device configuration. Both the firmware and software are classified as a "minor level of concern" since both components do not control aspects of the system that might impact patient safety. As such, a failure or latent flaw in the software or firmware will not pose any risk of harm to the patient or user.

12. Clinical Testing

The MiVu Mucosal Integrity Testing System (MiVu System) utilizing the MiVu Esophageal Endo Cap was tested against the same MiVu System utilizing the predicate MiVu Balloon Probe to demonstrate equivalence in a clinical environment and to validate usability requirements.

Under the auspices of an IRB, clinical studies were performed by three gastroenterologists at the same United States located facility who were familiar with both MiVu System configurations. Seventeen (17) random patients were tested using both devices to obtain comparative studies. An additional seven (7) random patients were tested using only the MiVu Esophageal Endo Cap device because the physician chose not to perform the balloon study based on the patient's condition and/or time constraints but preferred to acquire an Esophageal Endo Cap study. Patients were of adult age ranging from 20 to 70 years, with 12 males, 8 females and 4 unknowns (data not provided). Study patients were selected based on the known or highly suspected esophageal disease type (GERD, non-GERD, EoE), and their willingness to consent to the study. Since both the balloon probe study and the Endo Cap study were performed in conjunction with an endoscopic study, the patients were sedated. All studies were completed with no patient adverse effects or complications reported.

All studies found the MiVu System with the MiVu Esophageal Endo Cap device provided clinically equivalent or better results than the MiVu Balloon Probe based on the disease probabilities generated by the MiVu System.

13. Conclusion

The MiVu Mucosal Integrity Testing System (MiVu System) utilizing the MiVu Esophageal Endo Cap device has a substantially equivalent indications for use and intended use to the MiVu System utilizing the predicate MiVu Balloon Probe.

Based on the technological characteristics and overall performance of the devices in bench testing and clinical testing, Diversatek Healthcare believes the proposed MiVu Mucosal Integrity Testing System utilizing the MiVu Esophageal Endo Cap and the predicate device configuration are substantially equivalent.

Through risk assessment and testing, Diversatek Healthcare has concluded the MiVu Mucosal Integrity Testing System utilizing the MiVu Esophageal Endo Cap does not raise any new issues of safety and effectiveness and performs as well as the legally marketed predicate device.