October 3, 2019

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

Re: K190208
Trade/Device Name: Diversatek Healthcare High Resolution Impedance Manometry (HRiM) Probe
Regulation Number: 21 CFR 876.1725
Regulation Name: Gastrointestinal motility monitoring system
Regulatory Class: II
Product Code: FFX
Dated: September 17, 2019
Received: September 18, 2019

Dear Laura Boll:

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,

Martha Betz, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190208

Device Name
Diversatek Healthcare High Resolution Impedance Manometry (HRiM) Probe

Indications for Use *(Describe)*
The High Resolution Impedance Manometry (HRiM) Probe is intended for use by gastroenterologists, surgeons, and medically trained personnel for gastrointestinal tract studies to obtain a high resolution mapping of peristaltic activity or pressure within the organs of the gastrointestinal tract, and to allow storage of the corresponding data.

The device is used in conjunction with a manometry system. Studies performed with this system require a skilled interpretation by a physician to aid in making a diagnosis of gastrointestinal motility disorders.

The device is indicated for use on adult populations only.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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 (formerly Sandhill Scientific)
Submitter's Address:	9150 Commerce Center Circle Highlands Ranch, CO 80129
Establishment Registration No.:	2023374
Contact Person:	Laura Boll Vice President, Quality and Regulatory Affairs
Telephone:	414-755-4806 (direct) 414-265-7620 ext. 4806
Email:	lboll@diversatek.com

Date Prepared: December 7, 2018
Date Revised: September 26, 2019

2. Device Identification

Trade Device Name:	Diversatek Healthcare High Resolution Impedance Manometry (HRiM) Probe
Common Device Name:	HRiM Probe
FDA Product Code	FFX
FDA Classification Name:	Gastrointestinal Motility Monitoring System
Regulation Number:	21 CFR 876.1725
Regulatory Class:	II

3. Predicate Device Identification

Predicate 510(k) No.:	K062222
Predicate Trade Name:	Unisensor UniTip High Resolution GI Catheter
Predicate FDA Product Code:	FFX
Predicate FDA Classification Name:	Gastrointestinal Motility Monitoring System
Predicate Regulation No.:	21 CFR 876.1725
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. General Device Description

The Diversatek Healthcare High Resolution Impedance Manometry (HRiM) Probe is a flexible polyurethane tube with a series of pressure and impedance sensors evenly spaced along the distal section of the device, an atraumatic tip, and a proximal end electrical connector/handle with an internal signal processor.

This probe is used in conjunction with the Sandhill Scientific[1] Gastrointestinal Motility System (K012232). This motility system consists of a Central Unit, an Interface Cable, Software, and a system cart to organize and hold the system components and computer. The Central Unit receives and conditions electrical signals from the probe to display manometric information through the software. The predicate probe from Unisensor currently uses this same Sandhill Scientific[1] Gastrointestinal Motility (Manometry) system. The overall system provides information to trained clinicians as an aid in documenting and diagnosing digestive motility disorders. The probe is the primary patient measurement device during a gastrointestinal tract motility study.

The HRiM Probe pressure transducers produce electrical signals that vary in direct proportion to the magnitude of the applied pressure from muscular contractions (peristalsis) within the gastrointestinal tract. The pressure sensor elements are semiconductor strain gauge devices that convert the applied external forces to proportional electrical signals. These pressure sensors each have a unique digital address controlled by the internal signal processor in the proximal end connector/handle of the probe. The probe uses a time multiplexor that generates the address of the pressure sensor to activate, sends that request to the sensor, and then reads the results. Pressure during a motility study is used to assess GI tract clearance via peristalsis.

In addition to pressure sensors for monitoring peristalsis, the probe also contains impedance sensors to provide data to assess bolus transit dynamics. The impedance sensor data is used to detect the direction and transition time of the fluid or food bolus in the GI tract by making use of their natural conductivity. These sensors are made from stainless steel and are designed to show relative impedance changes between GI tract baseline impedance and the impedance seen when a fluid/bolus passes the sensors.

Using pressure (manometry) and impedance together clarifies which patients with manometric abnormalities may have GI tract function disorders.

5. Intended Use

The High Resolution Impedance Manometry (HRiM) Probe is intended for use by gastroenterologists, surgeons, and medically trained personnel for gastrointestinal tract studies to obtain a high resolution mapping of peristaltic activity or pressure within the organs of the gastrointestinal tract, and to allow storage of the corresponding data.

[1] Please note that Sandhill Scientific was purchased by Diversatek Healthcare in December 2013 and is currently undergoing a name change from Sandhill Scientific to Diversatek Healthcare

The device is used in conjunction with a manometry system. Studies performed with this system require a skilled interpretation by a physician to aid in making a diagnosis of gastrointestinal motility disorders.

The device is indicated for use on adult populations only.

6. Technological Characteristics

The following table is a summary of the Diversatek Healthcare HRiM Probe technological characteristics as compared to the predicate device from Unisensor.

Table 5.1 Summary of design, features and principles of operation between the Diversatek Healthcare HRiM Probe and Predicate Device Unisensor UniTip High Resolution Catheter

Characteristic	**Diversatek Healthcare**	**Unisensor**
Trade Name	High Resolution Impedance Manometry(HRiM) Probe	UniTip High Resolution Catheter
510(k) Number	TBD	K062222
Product Code	FFX	FFX
Regulation Number	876.1725	876.1725
Regulation Name	Gastrointestinal motility monitoring system	Gastrointestinal motility monitoring system
Manufacturing Design	Thermoplastic catheter tubing with pressure and impedance sensors, atraumatic tip, and proximal electrical connector	Thermoplastic catheter tubing with pressure and impedance sensors, atraumatic tip, and proximal electrical connector
Materials	Polyurethane tubing, stainless steel impedance rings, ceramic piezoelectric pressure sensors, silicone encapsulate	Polyurethane tubing, stainless steel impedance rings, ceramic pressure sensors, silicone encapsulate
System Compatibility	Gastrointestinal Motility (Manometry) System (inSIGHT Ultima® System from Diversatek Healthcare) Reference: K012232	Gastrointestinal Motility (Manometry) System (inSIGHT Ultima® System from Diversatek Healthcare) Reference: K012232

Characteristic	Diversatek Healthcare	Unisensor
Intended Use	The High Resolution Probe is intended for use by gastroenterologists, surgeons, and medically trained personnel for gastrointestinal tract studies to obtain a high resolution mapping of peristaltic activity or pressure within the organs of the gastrointestinal tract, and to allow storage of the corresponding data. The device is used in conjunction with a manometry system.	The catheter probe is used to obtain a high resolution mapping of peristaltic activity or pressure within the organs of the gastrointestinal tract, and to allow storage of the corresponding data.
Environment	Professional Healthcare Office Environment, which includes hospitals, clinics, practitioner offices, and clinical laboratories	Professional Healthcare Office Environment, which includes hospitals, clinics, practitioner offices, and clinical laboratories
Patient Population	No special patient population; patients requiring GI tract function testing Adult use only	No special patient population; patients requiring GI tract function testing Adult use only
Patient Contact Categorization	Gastrointestinal Tract	Gastrointestinal Tract
Configuration	Non-sterile reusable device requiring high level disinfection before use	Non-sterile reusable device requiring high level disinfection before use
Reusable Device	Yes Reusable medical devices initially supplied as non-sterile to the user and requiring the user to process (i.e., clean, clean and disinfect, or clean and sterilize) the device for initial use, as well as to reprocess the device after each use	Yes Reusable medical devices initially supplied as non-sterile to the user and requiring the user to process (i.e., clean, clean and disinfect, or clean and sterilize) the device for initial use, as well as to reprocess the device after each use
Shelf Life	200 uses (2 years)	200 uses (2 years)

7. Non-Clinical Performance Data

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

a. Compatibility with Gastrointestinal Motility (Manometry) System

Mechanical compatibility of the Diversatek Healthcare HRiM Probe with the designated Gastrointestinal Motility (Manometry) System was tested by connecting the Diversatek HRiM Probe (HRMR201-000) to the accessory cable (H12R-7610) which connects to the motility system central unit (inSIGHT Ultima® H12R-2000).

b. Probe Communication to Gastrointestinal Motility (Manometry) System

The Diversatek Healthcare HRiM Probe functional testing was started by demonstrating probe communication of pressure and impedance data through the serial communication interface of the Probe connector to the System central unit (inSIGHT Ultima® H12R-2000). This test verified the firmware and software functionality of the HRiM Probe with the Gastrointestinal Motility (Manometry) System.

c. Comparison to Predicate Function and Performance

The Diversatek Healthcare HRiM Probe performance and function was tested against the predicate device from Unisensor to demonstrate equivalence. This testing included a comparison of the pressure sensor spacing, pressure sensor span, pressure sensor location, pressure sensor module diameter, pressure sensor sensitivity, impedance channel measurements, and depth marking on the probe catheters to aid in placement. The testing ran through the ranges of pressure and impedance measurements to simulate clinical use in a motility study and compared the results of the Diversatek Healthcare HRiM Probe to the predicate probe from Unisensor. The HRiM Probe was then subjected to reprocessing, simulated use of 200 cycles, and aging for 2 years per ASTM F1980-16. Pressure and impedance sensor functions were verified after this to demonstrate the device performance is not affected by reprocessing, the stresses of use, and/or aging. Additionally, the reprocessed/simulated use/aged probe joints were tested for strength and integrity per BS EN 1618.

d. Safety

Diversatek Healthcare confirmed the safety of the HRiM Probe through risk assessment, biocompatibility testing, and electrical safety testing.

Biocompatibility testing was completed on the Diversatek Healthcare HRiM Probe per ISO 10993-1. This device complies with all applicable parts of the standard. Complete test reports are in Section 15 of this Submission.

Electrical safety and EMC testing were conducted on the Diversatek Healthcare HRiM Probe. This device complies with the applicable requirements of IEC 60601-1-2:2014 (Ed 4) and IEC 60601-1:2005 (Ed 3) + Corr. 1:2006 + Corr. 2:2007 + A1:2012. Complete test reports are in Section 17 of this Submission.

e. Reusability / Shelf Life

The Diversatek Healthcare HRiM Probe was designed to withstand 200 cleaning / disinfection cycles followed by 200 simulated intubation / extubation cycles. The predicate device is also labeled with a 200 uses / 2 year warranty. Since function of

both HRiM probes is confirmed during procedural setup. This test was performed on a section of the probe that is representative of the probe and simulated 200 probe life cycles including air calibration, intubation, manometry procedure, extubation, cleaning/disinfection, and storage. The test articles were then subjected to the equivalent of 2 years of aging per accelerated aging standard ASTM F1980-16. The probe sensor function was verified after aging/200 life cycles.

f. Reprocessing

The HRiM Probe is a reusable device that requires reprocessing after each use. This reusable device falls within the scope of FDA Guidance document *"Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*", issued March 17, 2015. The validation covered the reprocessing instructions outlined in the HRiM Probe IFU, which included manual cleaning to remove gross contaminants followed by high level disinfection.

8. Electrical Testing

Electrical safety and EMC testing were conducted on the Diversatek Healthcare HRiM Probe. This device complies with the applicable requirements of IEC 60601-1-2:2014 (Ed 4) and IEC 60601-1:2005 (Ed 3) + Corr. 1:2006 + Corr. 2:2007 + A1:2012.

9. Software (Embedded Firmware) Verification and Validation

The High Resolution Impedance Manometry (HRiM) Probe contains embedded firmware. Verification and validation testing was conducted per FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". The software for this device was considered a "minor" level of concern since failure or latent flaw in the software will not pose any risk of harm to the patient or user.

Diversatek Healthcare reviewed and collected the information needed to address the cybersecurity issues as recommended in Section 6 of the FDA guidance titled "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices". This included a review of the following areas: protection from malware during the production and distribution of the software, continued support of the product after it has been introduced into the field, traceability for cybersecurity, and cybersecurity risk analysis and management. Based on that information, a Cybersecurity section was included within the HRiM Probe IFU.

10. Clinical Testing

Clinical testing was deemed unnecessary to support substantial equivalence. The non-clinical testing performed supports safety and efficacy of the device and provides data to show substantial equivalence to the predicate device.

11. Conclusion

Diversatek Healthcare HRiM Probe has the same intended use as the predicate device.

Based on the technological characteristics and overall performance of the devices in bench testing, Diversatek Healthcare believes the proposed HRiM Probe and the predicate device are substantially equivalent.

Through risk assessment and bench testing, Diversatek Healthcare has concluded the HRiM Probe does not raise any new issues of safety and effectiveness and performs as well as the legally marketed predicate device.

Based on the results of the non-clinical testing, Diversatek Healthcare has concluded the HRiM Probe is as safe, as effective, and performs as well as the legally marketed predicate device.