March 8, 2018

THD SpA
Maurizio Pantaleoni
Quality Assurance
Via dell'Industria 1
Correggio, 42015
Italy

Re: K180135
Trade/Device Name: THD Anopress with THD SensyProbe
Regulation Number: 21 CFR§ 876.1725
Regulation Name: Gastrointestinal Motility Monitoring System
Regulatory Class: II
Product Code: KLA
Dated: January 15, 2018
Received: January 17, 2018

Dear Maurizio Pantaleoni:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Charles Viviano -S

For Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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)*
K180135

Device Name
THD Anopress with THD SensyProbe

Indications for Use *(Describe)*

The THD Anopress device must be used exclusively to assess the average sphincter tone due to the pressure exerted by the muscles in the anal canal on the specially designed THD Probes. THD Anopress must only be used by appropriately trained medical staff.
Furthermore, the THD SensyProbe enables evaluation of rectal sensitivity and capacity and the ano-rectal inhibitory reflex through connection to a syringe and filling of the balloon on the probe with air.
The THD Anopress with THD SensyProbe is intended to be used in adults 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary of the THD ANOPRESS with THD SensyProbe

This 510(k) Summary is being submitted as required by **21 CFR 807.92.**

1. General Information

Submitter: THD SPA
Via dell'Industria 1, Correggio (RE), 42015, Italy
Tel. +39 0522 634311
Fax +39 0522634371

Consultant/ Contact: Maurizio Pantaleoni
THD SPA
Via dell'Industria 1, Correggio (RE), 42015, Italy
Mob. +393484435155
Tel. +39 0522 634311
Fax +39 0522 634371
Email: regulatory@thdlab.com

Summary Prepared Date: 01/10/2018

2. Names & Classification

Trade Name: THD ANOPRESS with THD SensyProbe
Common Name: Anorectal Manometry System
Classification name: Gastrointestinal motility monitoring system
Class II
Regulation Number and Product Code: 21 CFR 876.1725; KLA

3. Predicate Devices

The THD ANOPRESS WITH THD SENSYPROBE is substantially equivalent to the following devices:

Applicant	Device name	510(k) Number
THD SpA	**THD Anopress**	**K161785**
Medspira	**Mcompass**	**K120088**

4. Device Description

THD Anopress with THD SensyProbe is a handheld, portable anorectal manometry device for its use on patients requiring anorectal pressure studies and evaluation of functional rectal and pelvic diseases.

The subject device consists of two main components:

- THD Anopress: This is the main unit with a keyboard for the selection of input command for pressure measurement and display for the visualization of detected pressure parameters in real time;
- THD Probes, grouped in THD PressProbe and THD SensyProbe
    - THD PressProbe is non-sterile disposable probe to be connected via the dedicated Luer-Lock connector to the THD Anopress. The probe is charged with air by the pump contained into the THD Anopress main unit and then is introduced into the anal canal of patient for the detection of pressure.
    - THD SensyProbe keeps the same characteristics of the THD PressProbe but it is additionally featured with a balloon positioned on the top of the introducer that is designed to be filled with air by the mean of a second inflation line and a Luer-Lock connection with a syringe. The inflation of the balloon with air allows the evaluation of the sensation thresholds of the lower rectum and to assess and trigger what is known as Recto Anal Inhibitory Reflex (RAIR).

THD Anopress may be used in conjunction with a PC for data storage (not provided with THD Anopress). For this purpose, the PC requires installation of a dedicated program (Anopress SW) and the insertion of the Bluetooth Dongle accessory into the USB port. The Bluetooth dongle as well as Anopress SW are optionally provided by THD SpA.

THD PressProbe membrane has a diameter varying from 14,4 mm (empty membrane) to 16,6 mm (membrane inflated to 150 mmHg).
THD PressProbe is inflated to 150 mmHg, then it is inserted in the anal canal so that the sphincter exerts a compression on the membrane until 390 mmHg.

THD SensyProbe membrane has the same diameter and performances as the THD PressProbe. The additional balloon positioned on the top of the introducer reaches a diameter of 70 mm when inflated with 200 ml of air. The allowed maximum inflation volume for distal end balloon is 180 ml of air.

5. Indications for Use

The THD Anopress device must be used exclusively to assess the average sphincter tone due to the pressure exerted by the muscles in the anal canal on the specially designed THD Probes. THD Anopress must only be used by appropriately trained medical staff.
Furthermore, the THD SensyProbe enables evaluation of rectal sensitivity and capacity and the ano-rectal inhibitory reflex through connection to a syringe and filling of the balloon on the probe with air.
The THD Anopress with THD SensyProbe is intended to be used in adults only.

A comparison of the intended use of the proposed device and the predicate devices is provided in the table below:

Intended use comparison			
	Proposed device THD Anopress with THD SensyProbe	**Predicate device THD Anopress K161785**	**Predicate device mcompass K120088**
Indications for use	The THD Anopress device must be used exclusively to assess the average sphincter tone due to the pressure exerted by the muscles in the anal canal on the specially designed THD Probes. THD Anopress must only be used by appropriately trained medical staff. Furthermore, the THD SensyProbe enables evaluation of the rectal sensitivity and capacity and the ano-rectal inhibitory reflex through connection to a syringe and filling of the balloon on the probe with air. The THD Anopress with THD SensyProbe is intended to be used in adults only.	The THD Anopress device must be used exclusively to assess the average sphincter tone due to the pressure exerted by the muscles in the anal canal on the specially designed THD Press Probe. THD Anopress may only be used by appropriately trained medical staff.	The mcompass Anorectal Manometry System is for use on patients requiring anorectal pressure or sensation testing.

6. Comparison of technological characteristics with the predicate devices

Characteristics	THD AnoPress with THD SensyProbe	THD AnoPress (K161785)	Mcompass Anorectal Manometry System (K120088)

Composition	• Manometer
	• Inflating system: pump (on THD Anopress main unit) for manometry test and syringe for sensation test
	• Software on the THD Anopress device
	• Software on PC (optional)
	• Catheter (probe) :
	  ○ with one sensitive balloon (membrane) located on the introducer (THD PressProbe). Membrane is related to manometry test
	  ○ with one sensitive balloon (membrane) located on the introducer and one larger balloon located in the most distal end (THD SensyProbe). Membrane is related to manometry test, the larger balloon is related to rectal sensation test.
		• Manometer
		• Inflating system: pump (on THD Anopress main unit)
		• Software on the THD Anopress device
		• Software on PC (optional)
		• Catheter (probe) with one sensitive balloon (membrane) located on the probe introducer
			• Manometer
			• Inflating system: syringe
			• Software
			• Catheter (probe) with four sensitive balloons located on the distal end of the catheter and connected to pressure transducers (manometry test). In addition, a larger balloon located in the most distal end of the catheter is connected to a fifth pressure transducer and is used to measure pressure and to simulate a various bowel levels (rectal sensation test)

Pressure Data Transmission	Wireless ; in real time	Wireless ; in real time	Wireless ; in real time

Mechanism of action	Air-charged probe for: • measuring anal pressure for manometry test, by the mean of a membrane on the probe introducer (all THD Probes) • evaluation of RAIR and rectal sensation, by the mean of a distal end sensation balloon (only THD SensyProbe)	Air-charged probe for : • measuring anal pressure for manometry test, by the mean of a membrane on the probe introducer	Air-charged probe for : • measuring local anorectal pressure, by the mean of four sensitive balloons located on the distal end of the catheter • evaluation of the RAIR and rectal sensation, by the mean of a balloon located on the most distal end of the catheter
Detected parameters	• Resting Pressure • Squeeze Pressure • Endurance • Strain Pressure • Squeeze/Rest Rate • Real Time Pressure Measurement • Anal Contractile Reflex • Cough Reflex • Rectal Sensation Thresholds • RAIR	• Resting Pressure • Squeeze Pressure • Endurance • Strain Pressure • Squeeze/Rest Rate • Real Time Pressure Measurement • Anal Contractile Reflex • Cough Reflex	• Resting Pressure • Squeeze Pressure • Endurance • Strain Pressure • Squeeze/Rest Rate • Real Time Pressure Measurement • Anal Contractile Reflex • Cough Reflex • Rectal Sensation Thresholds • RAIR
Component in contact with patient	Disposable Catheter (membrane and distal end balloon)	Disposable Catheter (membrane)	Disposable Catether (sensitive balloons)
Materials patient contacting	Poly-urethane (membrane) C-Flex (SEBS – Styrene-ethilene-butadiene-styrene block polymer (distal end balloon)	Poly-urethane (membrane)	Urethane
Sterility	Non sterile	Non sterile	Non sterile

7. Performance data

1) The following non clinical tests are referenced from the predicate device THD Anopress K161785, due to the components not changing:

Non clinical Performance test Summary referenced from K161785 - THD AnoPress		
Characteristics	**Reference standards**	**Results**
Biocompatibility	• ISO 10993-1 • ISO 10993-5 • ISO 10993-10	Obtained results demonstrate compliance to the standards
Electrical safety	• IEC 60601-1	Obtained results demonstrate compliance to the standard
EMC	• IEC 60601-1-2	Obtained results demonstrate compliance to the standard
Software Verification and Validation	• IEC 62304	Obtained results demonstrate compliance to the standard
Functional Performance and accuracy verification in simulated use conditions	• Verification of functional performances and accuracy of the THD Anopress at: ○ Strain pressure ○ Squeeze pressure ○ Resting pressure using different THD Anopress and different THD PressProbe	The performances and the accuracy obtained are comparable with the predicate devices for all the products tested.

Non clinical Performance test Summary referenced from K161785 - THD PressProbe		
Characteristics	**Test Performed**	**Results**
Mechanical Performance Tests (new and aged devices)	• Verification of geometric specifications (length and diameter) • Verification of membrane expanded / unexpanded diameter • Verification of membrane and tubing leak testing • Verification of membrane expanded / unexpanded diameter after repeated use • Verification of membrane and tubing leak testing after repeated use • Verification of membrane maximum volume • Verification of functional performance of the THD Anopress main unit (strain, squeeze, resting) with not aged/aged THD PressProbes • Verification of the membrane burst pressure • Tensile testing of the joints and bonded components of the tubing • Verification of the peeling of the joints and bonded components of the membrane	The performances and the accuracy obtained are comparable with the predicate devices for all the products tested.

2) The following non clinical tests were performed on the subject device:

Non clinical Performance test Summary - THD SensyProbe		
Characteristics	**Test Performed**	**Results**
Mechanical Performance Tests (new and aged devices)	• Verification of geometric specifications of distal end balloon • Verification of inflation performances of the distal end balloon • Distal end balloon and tubing leak testing (supplemental inflation line) • Distal end balloon expanded / un-expanded diameter – repeated use • Distal end balloon and tubing leak testing – repeated use (supplemental inflation line) • Distal end balloon maximum burst volume • Tensile testing of the joints and bonded components of the tubing (supplemental inflation line) • Testing of the joints and bonded components of the distal end balloon	The performances obtained are comparable with the predicate device K120088 (mcompass) for all the products tested.

3) Clinical literature used to support the indications for use:

- **An ANMS-NASPGHAN consensus document on anorectal and colonic manometry in children** - Rodriguez L, Sood M, Di Lorenzo C, Saps M, Neurogastroenterol Motil. 2017 Jan;29(1). doi: 10.1111/nmo.12944. Epub 2016 Oct 9
- **Clinical applications of gastrointestinal manometry in children** – Jeana Hong - Pediatr Gastroenterol Hepatol Nutr. 2014 Mar; 17(1): 23–30.
- **Anorectal manometry in the neonatal diagnosis of Hirschsprung's disease** - Enríquez Zarabozo E, Núñez Núñez R, Ayuso Velasco R, Vargas Muñoz I, Fernández de Mera JJ, Blesa Sánchez E, , Cir Pediatr. 2010 Jan;23(1):40-5
- **A clinical evaluation of anorectal pressure studies in the diagnosis of Hirschprung's disease** – Ian Aaronson and H.H. Nixon – Gut. 1972;13:138-146

8. Conclusions

In light of evidences summarized above and based on classification, intended use, technological characteristics and performance data, the subject device is substantially equivalent to the predicate devices **K161785** and **K120088**.