DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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March 14, 2017

THD S.p.A.
% Maurizio Pantaleoni
CEO of Isemed (THD's Consultant)
ISEMED S.R.L.
Via A. Altobelli Bonetti 3/A
Imola, BO 40026
Italy

Re: K161785
Trade/Device Name: THD ANOPRESS
Regulation Number: 21 CFR§ 876.1725
Regulation Name: Gastrointestinal Motility Monitoring System
Regulatory Class: II
Product Code: KLA
Dated: February 3, 2017
Received: February 8, 2017

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Joyce M. Whang -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161785

Device Name
THD ANOPRESS

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 Press Probe. THD Anopress may only be used by appropriately trained medical staff.

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.

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510(k) Summary of the THD ANOPRESS

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

1. General Information

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Summary Prepared Date: 07/03/2017

2. Names & Classification

Trade Name: THD ANOPRESS
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 is substantially equivalent to the following device:

Applicant	Device name	510(k) Number
Medspira	**Mcompass**	**K120088**

4. Device Description

THD Anopress is a handheld, portable anorectal manometry device for measuring anal pressure, and especially the average sphincter tone, at the bedside on adult patients population.

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 Press Probe: This is a 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 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 Press Probe is inflated to 150 mmHg, then it is inserted in the anal canal so that the sphincter exerts a compression on the membrane until 390mmHg.

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 Press Probe. THD Anopress may only be used by appropriately trained medical staff.

6. Comparison of technological characteristics with the predicate device

Characteristics	THD AnoPress	Mcompass Anorectal Manometry System (K120088)
Composition	• manometer • Inflating system: pump • Software on manometer • Software on PC(optional) • catheter (probe) with one sensitive balloon	• manometer • inflating system: syringe • Software • catheter (probe) with 5 sensitive balloons
Pressure Data Transmission	Wireless ; in real time	Wireless ; in real time
Mechanism of action	Air-charged probe for measuring anal pressure	Air-charged probe for measuring local anorectal pressure

Characteristics	THD AnoPress	Mcompass Anorectal Manometry System (K120088)
Detected parameters	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
Component in contact with patient	Disposable Catheter (sensitive balloon)	Disposable Catether (sensitive balloon)
Materials patient contacting	Poly-urethane	Urethane
Sterility	Non sterile	Non sterile

7. Performance data

1) Non clinical tests performed on the subject device:

Non clinical Performance test Summary-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 ad accuracy of the THD Anopress at : o Strain pressure o squeeze pressure o resting pressure using different THD AnoPress and different THDPress-Probe	The performances and the accuracy obtained are comparable with the predicate device for all the products tested.

Non clinical Performance test Summary-THD Press Probe		
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 (strain, squeeze, resting) with not aged/aged Press Probes. • Verification of the membrane burst pressure • Verification of tensile testing of the joints and bonded components of the tubing • Verification of the peeling of the joints and bonded components of the membrane	No differences in results between aged and not aged samples. When applicable the relevant performances of THD AnoPress and THD PressProbe are comparable with the performances of the predicate device.

2) Clinical tests performed on the subject device:

N/A: No clinical tests were performed on the subject device.

8. Conclusions

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