THD SpA
℅ Maurizio Pantaleoni
Quality and Regulatory Manager
Via dell'Industria, 1
Correggio, RE 42015
ITALY

June 24, 2021

Re: K211623
Trade/Device Name: THD Procto Software System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO, KLA, ITX, FWG, OUG, NSX
Dated: May 19, 2021
Received: May 26, 2021

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. 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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)*
K211623

Device Name
THD Procto Software System

Indications for Use *(Describe)*

The THD Procto Software System is a software that can be used:

• In endoanal ultrasound (EAUS), in order to help evaluate pelvic floor disorders by processing and recording images of tissue structures in the pelvic region with the aid of a dedicated ultrasound probe. This is done by inserting the probe into the anal canal, acquiring the ultrasound signal and letting the software process the image.

• In Anoscopy exams, in order to record images and videos of the anorectal channel, which are acquired through a dedicated video camera that provides images with an adequate resolution and their subsequent processing.

• In anorectal manometry examinations, in order to view on a two-dimensional Pressure/Time graph the acquisition of the mean pressure signal transmitted by the THD Anopress device and subsequent processing (examination report and report printing)

• Follow the clinical history, possible follow-ups of a patients

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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1. General Information

Submitter :

THD SpA
Via dell'Industria 1
Correggio (RE) 42015, Italy
Tel. +39 0522 634311
Fax +39 0522 634371

Establishment Registration Number: 3006680097

Contact:

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

Summary Preparation Date: May 19, 2021

2. Name & Classification

Device Name: THD Procto Software System

Classification name: Ultrasound Pulsed Echo Imaging System

Classification regulation number: 892.1560

Primary Product Code: IYO

Additional Product Codes: KLA, ITX, FWG, OUG, NSX

CLASS: II

3. Predicate Devices

THD Procto Software System covered by this Special 510(k) is substantially equivalent to the following devices

Applicant	Device name	510(k) Number
THD S.p.A	THD Procto Software System	K193512
THD S.p.A	THD Anopress with THD SensyProbe	K180135

The device modification is related to the THD Procto Software System, already cleared by the Agency with K193512. K193512 is then the primary predicate device for this device modification.

The modified device consists in the addition of a new module to the THD Procto Software (namely the Manometry Module) that can communicate with the hardware device THD Anopress during the execution of anorectal manometry exams. THD Anopress is cleared by the Agency with K180135.

In the initial design of THD Anopress device, a dedicated software, named Anopress SW, was developed in order to allow the Bluetooth communication with THD Anopress device during anorectal manometry exams for patient and examination data storage.

Device modification of THD Procto Software System aims to provide a single software suite able to interface with different hardware devices commonly used in the proctology field, through the management of separate and independent modules, by integrating the Anopress SW in the THD Procto Software with an additional independent module, named Manometry Module.

The main features of the Manometry Module are summarized below:

- Communication with THD Anoperss device through USB Dongle Bluetooth technology
- When THD Anopress device is connected and the manometry exam is in progress, the Manometry Module allows the acquisition of the patient manometric data provided by the THD Anopress hardware device and subsequent visualization on a two-dimensional Pressure/Time graph
- Post processing elaboration by the operator of the acquired two-dimensional Pressure/Time graph with the possibility to change the positioning and size of the time intervals defining the manoeuvres performed by the patient
- Examination reporting (anamnesis, comments, conclusions) and report printing

The previous existing modules, e.g. Launcher, Endoanal Ultrasound (EAUS) and Anoscopy modules, are not affected by this device modification.

4. Device Description

The **THD Procto Software System,** is a diagnostic system intended to be used to investigate pelvic floor disorders, and specifically the THD Procto Software together with its accessories and devices (endoanal probe, video camera and THD Anopress), is able to be applied for:

- Endoanal ultrasound (→ trans-rectal ultrasound / echography)
- Anoscopy exams
- Manometry exams

During Endoanal Ultrasound the **THD Procto Software System** processes and records images of tissue structures in the pelvic region with the aid of a dedicated *ultrasound probe;*
During Anoscopy exams the **THD Procto Software System** records and displays images of the anorectal channel with the aid of a dedicated *video camera;*

During Manometry exams the **THD Procto Software System** allows the visualization and storage of patient data and examination results (anorectal manometry pressure values) as measured by THD Anopress device.

The different modules and associated hardware devices cannot interfere with each other neither can work simultaneously.

5. Indications for Use

The THD Procto Software System is a software that can be used:

- In endoanal ultrasound (EAUS), in order to help evaluate pelvic floor disorders by processing and recording images of tissue structures in the pelvic region with the aid of a dedicated ultrasound probe. This is done by inserting the probe into the anal canal, acquiring the ultrasound signal and letting the software process the image.
- In Anoscopy exams in order to record images and videos of the anorectal channel, which are acquired through a dedicated video camera that provides images with an adequate resolution and their subsequent processing.
- In anorectal manometry examinations, in order to view on a two-dimensional Pressure/Time graph the acquisition of the mean pressure signal transmitted by the THD Anopress device and subsequent processing (examination report and report printing)
- Follow the clinical history, possible follow-ups of a patients

6. Design Control Activities

The device modification is related to the addition of a new module to the THD Procto Software already cleared by the Agency with K193512, namely the Manometry Module. This new module interfaces with the hardware device THD Anopress, cleared by the Agency with K180135. The new Manometry module keeps the same features and functionalities of the Anopress SW that is the initial software application designed to communicate with the THD Anopress device during manometry exams.

The design control activities performed on the modified devices aimed to the verification of the new features in relation to the risk analysis in order to assess the impact of this device modification, in compliance with the IEC62304, that is the standard normally used by THD to manages the development of its Software.

After verification and validation activities no unacceptable residual risks emerged from the risk analysis and all verification and validation activities performed on the subject modified device provided results conform to the required specifications.

7. Comparison of technological characteristics with the predicate devices

	Proposed Device	Primary Predicate device	Secondary Predicate device
Product Name	**THD Procto Software System**	**THD Procto Software System**	**THD Anopress with THD SensyProbe**
Manufacturer	**THD S.p.a**	**THD S.p.a**	**THD S.p.a**
510(K) No.	**K211623**	**K193512**	**K180135**
Classification			
• **Regulation Name**	- Ultrasound Pulsed Echo Imaging System - Gastrointestinal motility monitoring system	Ultrasound Pulsed Echo Imaging System	Gastrointestinal motility monitoring system
• **Regulation Number**	21 CFR 892.1560	21 CFR 892.1560	21 CFR 876.1725
• **Regulatory Class**	II	II	II
• **Primary Product Code**	IYO	IYO	KLA
• **Subsequent Product Code**	KLA, ITX, FWG, OUG, NSX	ITX, FWG, OUG	NSX
Intended use			
• **Indications for use**	The **THD Procto Software System** is a software that can be used: • In endoanal ultrasound (EAUS), in order to help **evaluate pelvic floor disorders** by processing and **recording images** of **tissue structures in the pelvic region** with the aid of a dedicated ultrasound probe. This is done by **inserting the probe into the anal canal**, acquiring the ultrasound signal and letting the software process the image. • In Anoscopy exams in order to record images and videos of the anorectal channel, which are acquired through a dedicated video camera that provides images with an adequate resolution and their subsequent processing • In anorectal manometry examinations, in order to view on a two-dimensional Pressure/Time graph the acquisition of the mean pressure signal transmitted by the THD Anopress device and subsequent processing (examination report and report printing) • Follow the clinical history, possible follow-ups of a patients	The **THD Procto Software System** is a software that can be used: • In endoanal ultrasound (EAUS), in order to help **evaluate pelvic floor disorders** by processing and **recording images** of **tissue structures in the pelvic region** with the aid of a dedicated ultrasound probe. This is done by **inserting the probe into the anal canal**, acquiring the ultrasound signal and letting the software process the image. • In Anoscopy exams in order to record images and videos of the anorectal channel, which are acquired through a dedicated video camera that provides images with a resolution greater than 1.1 MPx through USB protocol	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.
• **Anatomical site**	Anal canal	Anal canal	Anorectal tract

	Proposed Device	Primary Predicate device	Secondary Predicate device
Product Name	**THD Procto Software System**	**THD Procto Software System**	**THD Anopress with THD SensyProbe**
Manufacturer	**THD S.p.a**	**THD S.p.a**	**THD S.p.a**
510(K) No.	**K211623**	**K193512**	**K180135**
Technical Features			
• **Configuration of the system**	Standalone software, USB Endoanal probe and camera and possibility to communicate with the THD Anopress device with the specific Bluetooth Dongle available in the THD Anopress, to be inserted into the USB port of the PC in order to allow the bluetooth connection between the PC and the THD Anopress	Standalone software, USB Endoanal probe and camera	- USB key containing Anopress SW data acquisition software and Software Manual - Bluetooth Dongle to be inserted into the USB port of the PC to establish the connection with the THD Anopress.
• **Software platform**	Commercial off-the-shelf operating system (Windows)	Commercial off-the-shelf operating system (Windows)	Commercial off-the-shelf operating system (Windows)
• **Measurement function**	2D measurement: distances, area and angle measurement	2D measurement: distances, area and angle measurement	-
• **Commercial package**	THD Proctostation or THD ProctoMobile	THD Proctostation or THD ProctoMobile	- 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) : o with one sensitive balloon (membrane) located on the introducer (THD PressProbe). Membrane is related to manometry test o 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

8. Performance Data

Non clinical tests performed on the subject device

The software has been tested and validated according to the requirements of IEC 62304.

The subject device modification has been evaluated according to the following guidance documents:

- Guidance for the Content of Premarket Submission for Software Contained in Medical Devices: Guidance for Industry and Staff – Issued on May 11, 2005
- The Special 510(k) Program: Guidance for Industry and FDA staff – Issued on September 13, 2019
- Deciding When to Submit a 510(k) for a Software Change to an Existing Device: Guidance for Industry and FDA Staff – issued on October 25, 2017

In addition to performance data already documented with K193512, an integration test on the modified device has been performed in order to check the correct integration of the THD Procto Software, the subject device, with the THD Anopress device, verifying that the additional Manometry Module performs the expected functions and dialogues correctly with the THD Anopress device.

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 primary predicate device **K193512** for Medical Report (Launcher), Endoanal Ultrasound (EAUS) and Anoscopy modules.