THD SpA
% Filippo Bastia
CEO
Via dell'Industria,1
Correggio (RE) 42015
ITALY

January 26, 2020

Re: K193512
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, ITX, OUG, FWG
Dated: December 16, 2019
Received: December 18, 2019

Dear Filippo Bastia:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193512

Device Name
THD Procto Software System

Indications for Use *(Describe)*
The THD Procto Software 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

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.

1. General Information

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Establishment Registration Number: 3006680097

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Email: regulatory@thdlab.com

Summary Preparation Date: December 19, 2019

2. Name & Classification

Device Name: THD Procto Software System

Classification names	Regulation Name	Product Code
Ultrasound Pulsed Echo Imaging System	892.1560	IYO
Diagnostic ultrasonic transducer	892.1570	ITX
Surgical camera and accessories	878.4160	FWG
Medical Device data system	880.6310	OUG

CLASS: II

3. Predicate Devices

The THD Procto Software System is substantially equivalent to the following device:

Applicant	Device name	510(k) Number
Halo Medical Technologies	CatalySt, MidCRYSTL, HALO Ultrasound System	K140899 Predicate device
Interson Corporation	Interson USB Ultrasound System	K163443 Reference device

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 (endoanal probe and video camera), is able to be applied for:

- Endoanal ultrasound (→ trans-rectal ultrasound / echography)
- Anoscopy 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;*

The THD Procto Software consists of three macro modules or sub-parts, each one with its own function, as described below:

- Medical Report (Launcher) module, which contains the functions for the management of the patient database and of the Exams database. Patients and Exams databases support the operation of the remaining macro modules (Endoanal Ultrasound Module and Anoscopy Exams Module) that are listed below
- Endoanal Ultrasound Module, which manages:
    - The acquisition of the ultrasound signal from the probe and its processing to transform it into a two-dimensional echographic image / video
    - Any image / video processing (application of notes, zoom, measurements, etc.) in real-time (during the exam) or post-processing,
    - The examination report (medical history, comments, conclusions) and the printing
- Anoscopy Exams module, which manages:
    - Capturing images and video from the video camera via standard USB protocol. Images are then recorded and displayed on the computer screen
    - Any image / video processing (application of notes, zoom, measurements, etc.) in real-time (during the exam) or post-processing
    - The examination report (medical history, comments, conclusions) and the printing

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 a resolution greater than 1.1 MPx through USB protocol

6. Comparison of technological characteristics with the predicate devices

	Proposed Device	Predicate device	Reference device
Product Name	THD Procto Software System	CatalySt, MidCRYSTL, HALO Ultrasound System	Interson USB Ultrasound System
Manufacturer	THD Spa	Halo Medical Technologies	Interson Corporation
510(K) No.	/	K140899	K163443
Classification			
• Regulation Name	Ultrasound Pulsed Echo Imaging System	Ultrasound Pulsed Echo Imaging System	Ultrasonic pulsed doppler imaging system
• Regulation Number	21 CFR 892.1560 21 CFR 892.1570 21 CFR 878.4160 21 CFR 880.6310	21 CFR 892.1560 21 CFR 892.1570	21 CFR 892.1550
• Regulatory Class	II	II	II
• Product Code	IYO	IYO	IYN,
• Subsequent Product Code	ITX, FWG, OUG	ITX	IYO, ITX
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 a resolution greater than 1.1 MPx through USB protocol	"Catalyst" is a diagnostic ultrasound system designed to be used for investigating disorders of the pelvic floor. An ultrasonographic crystal within the probe records images of the organ, muscle, and tissue structures of the pelvic region. MidCRYSTL and HALO probes allow for ultrasonography of the following: 1) on the surface of the perineumn and/or abdomen, 2) endocavity, by inserting the endovaginal probe into the vagina, and 3) endocavity, by inserting the endoanal probe into the anal canal.	The Interson USB Ultrasound System is intended for diagnostic ultrasound imaging in B, color Doppler, or Combined (B + Color) modes. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: • Fetal/Obstetric • Abdominal • Pediatric • Small Organ • Musculo-skeletal (conventional) • Musculo-skeletal (superficial) • Urology • Gynecology • Pelvic Floor • Neuro-muscular • Peripheral Vessel The system is intended for use by healthcare professionals
• Anatomical site	Anal canal	Perineum and/or abdomen, vagina, anal canal	Every are in which ultrasonography is required – it include anal canal using the proper probe
Features			
• Configuration of the system	Standalone software, USB Endoanal probe and camera	Standalone software and USB dedicated pelvic floor probes	Standalone software and USB dedicated probes for different applications
• 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 measure distances and calculate angles	2D measurement and area measurement
• Commercial package	THD Proctostation or THD Procto mobile	"Catalyst" diagnostic ultrasound system	Unknown