MAR - 1 2011

510(k) Summary for the

Family of THD disposable Anoscopes, Proctoscopes, Rectoscopes and Light-scope

This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

2.1. General Information

Submitter:

THD S.p.A.
Via dell'Industria, 1
42015 - Correggio (RE)
Italy

Establishment Registration Number: 3006680097

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Summary Preparation Date: November 25, 2010

2.2. Names

Device Name: Family of THD disposable Anoscopes, Proctoscopes, Rectoscopes and Light-scope

Classification Name: Endoscope and accessories

Product Code: FER/GCP

Regulation number: 876.1500

2.3. Predicate Devices

This Special 510(k) is related to the device modifications of the following devices:

Applicant	*Device name*	*510(k) Number*
THD S.p.A.	Family of THD Disposable anoscopes, proctoscopes and rectoscopes	K091490

The Family of THD disposable Anoscope, Proctoscope, Rectoscope and Light-scope and its predicate device are indicated for the same intended use and have the same technology characteristics. Both families include the anoscopes, proctoscope and the rectoscopes manufactured with the same materials and with the same dimensions.

The only difference is that the Family of THD disposable Anoscope, Proctoscope, Rectoscope and Light-scope includes also a group of different models with a different handle:

- A type of handle for the use of the devices with an external light source
- A type of handle with a LED integrated light source

Moreover the new group of devices have the following modification

- The THD Light-scope models have a white tip
- The THD Light-scope rectoscopes have the lens without hole
- Some rectoscope models are packaged with a class I device: the inflation bulb

The modification of the handle consents to manufacture the devices with or without integrated light source. The model without light source are intended to be used with an external light source, which must be fitted on the devices as the previous cleared devices. The models with light source have the same functioning method of the previous cleared device, but they are ready to use for the physician.

The THD Light-scope models are designed with the white tip as the previous cleared rectoscope (K091490). This characteristic improves the light focus to the end of the device with a better visibility of the treated area.

The THD Light-scope rectoscope models with lens without hole are the same of the previous approved rectoscope (K091490), the only difference is that the stopper with lens at the initial part of the rectoscope is manufactured without hole.

2.4. Device Description

The Family of THD disposable Anoscope, Proctoscope, Rectoscope and Light-scope are disposable not sterile rectoscopes, proctoscopes and anoscopes with a light source external or integrated on the handle. The devices are designed for the examination and treatment of the anal (anoscopes) and rectum (proctoscopes and rectoscopes) examination.
The devices consist of transparent plastic anoscope, proctoscope or rectoscope for diagnostic or therapeutic use.
The Family of THD disposable Anoscope, Proctoscope, Rectoscope and Light-scope is made by two categories of devices:

- Diagnostic Anoscopes, Proctocope and Rectoscope
- Surgical Proctoscopes

The Family of THD disposable Anoscope, Proctoscope, Rectoscope and Light-scope include both models which require the external light source and models which not require the external light source, in this case the light source is integrated on the handle. The external light source is provided as accessory of the family and it can be the THD Shining Light and the THD pen light. The external light source THD Shining Light and the THD pen light have been already approved (K091490).

2.5. Indications for Use

The family of THD disposable Anoscope, Proctoscope, Rectoscope and Light-scope is intended for physician use to examine the anal sphincter, anus, rectum, and, using additional accessories, to perform various diagnostic and therapeutic procedures.

No changes in the Indications for use was occurred.

2.6. Design Control Activities

The risk analysis method used to assess the impact of the modifications is described in the Annex 4.3 - Risk management plan. The design verification tests were performed as a result of this risk analysis assessment (see attachment 4.2). The design verification tests are listed in the following table.

Modification	Test Performed	Acceptance Criteria
New handle designed without integrated light source	Design verification and effectiveness test	Safety and effectiveness of the device
New handle designed with a LED integrated light source	Design verification Safety and electromagnetic tests	Safety and effectiveness of the device
White tip in the new anoscope models	Design verification	Safety and effectiveness of the device
Lens without hole in the new rectoscope	Design verification	Safety and effectiveness of the device
New packaging of rectoscope with inflation bulb	Design verification and effectiveness test	Safety and effectiveness of the device

The test method used are the same as those submitted in the original submission.
A declaration of conformity with design controls is included in attachment 1.1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G60
Silver Spring, MD 20993-0002

THD S.p.A.
c/o Mr. Guido Bonapace
Regulatory Consultant & General Manager
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Imola, BO
ITALY 40026

MAR - 1 2011

Re: K103647
Trade/Device Name: Family of THD disposable Anoscope, Proctoscope, Rectoscope and Light-scope
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FER
Dated: February 3, 2011
Received: February 7, 2011

Dear Mr. Bonapace:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103647

Device Name: Family of THD disposable Anoscope, Proctoscope, Rectoscope and Light-scope

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ ___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K103647