

K091490

510(k) Summary for the

Rg 1 8 r

THD Anoscope, Proctoscope and Rectoscope

JUN 11 2009

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

Contact Person:

Guido Bonapace
ISEMED srl
Via Borgo Santa Cristina 12
40026 Imola (BO)
Italy
Mob.phone: +39-335-5378686
Telephone: +39-051-6527315
Fax: +39-051-6284344
Email: gbonapace@isemed.eu

Summary Preparation Date:

May 14, 2009

2.2. Names

Device Name:

Family of THD disposable anoscope,
proctoscope and rectoscope

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:

<i>Applicant</i>	<i>Device name</i>	<i>510(k) Number</i>
THD S.p.A.	Family of THD Disposable anoscope/proctoscope	K080132

K091490
Pg 2 of 2

2.4. Device Description

The family of THD Disposable Anoscope, Proctoscope and Rectoscope are designed for the examination and treatment of the anal (anoscope) and rectum (proctoscope and rectoscope) examination. The devices consist of transparent plastic anoscope, proctoscope or rectoscope for diagnostic or therapeutic use.

The family of THD disposable Anoscopes, Proctoscopes and Rectoscope is made by 2 categories of devices:

- Diagnostic Anoscopes, Proctoscopes and Rectoscope
- Surgical Proctoscopes

The family of THD disposable Anoscopes, Proctoscopes and Rectoscope consist of the evolution of the family of THD disposable Anoscope and proctoscope previously cleared (K080132).

As in the previous submission, this family is provided with two accessories for illumination the "Shining Light" and the "pen light".

2.5. Indications for Use

The family of THD disposable Anoscope, Proctoscope and Rectoscope 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
Dimensions of the proctoscope	Design verification	Safety and effectiveness of the device
Materials of the tip of new size devices	Biocompatibility	Medical Grade material
Sterilization of the rectoscopes	Sterilization Validation	See Sterilization Statement (Annex 5.1)

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



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

THD Spa
% Mr. Guido Bonapace
CEO
ISEMED S.R.L.
Via Borgo Santa Cristina 12
40026 Imola (BO)
ITALY

JUN 11 2009

Re: K091490

Trade/Device Name: Family of THD disposable anoscope, proctoscope and rectoscope
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FER
Dated: May 14, 2009
Received: May 20, 2009

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 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.

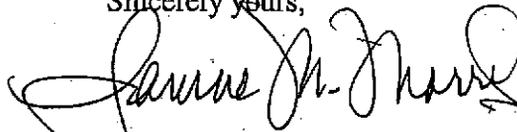
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 091490

Device Name: Family of THD disposable anoscope, proctoscope and rectoscope

Indications for Use:

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

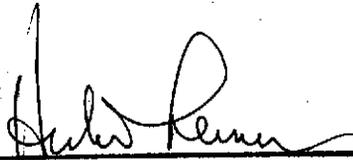
Prescription Use X
(Part 21 CFR 801 Subpart D)

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, Abdominal,
and Radiological Devices

510(k) Number K 091490