

**510(k) Summary
for the THD Spa - Family of "THD disposable Anoscope/ Proctoscope"**

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

1. General Information

Submitter: THD Spa
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Italy

APR 9 2008

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Summary Preparation Date: 14/01/2008

2. Names

Device Name: Family of "THD disposable
Anoscope / Proctoscope"

Classification: Regulation Description: Endoscope and accessories
Regulation number: 876.1500
Classification name: Anoscope and accessories
Endoscope, AC-powered and
accessories
Product Code: FER/GCP

3. Predicate Devices

The family of “THD disposable Anoscope/Proctoscope” are substantially equivalent to a combination of the following devices:

- ✓ Sapimed Self Light Disposable Anoscope (K070913)
- ✓ Sapimed Disposable Sigmoidoscope/Proctoscope (K070915)

4. Device Description

The family of “THD disposable Anoscope/Proctoscope” are designed for examination and treatment of the anal (Anoscope) and rectum (Proctoscope) examination and consists of transparent plastic disposable anoscopes and proctoscopes in sterile and non sterile conditions, for diagnostic or therapeutic use.

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

- Diagnostic Anoscopes and Proctoscopes
- Surgical Proctoscopes

Illumination is provided by a PenLight or by the “Shining Light” illuminator both supplied and manufactured by THD Spa. A PenLight is a battery powered illuminator while the “Shining Light” is AC powered. Both of these accessories are light sources employed to optimize the use of the anoscopes and proctoscopes.

The THD disposable Anoscopes and Proctoscopes and the accessories are equivalent to other legal marketed devices, as Sapimed devices, for classification, intended use, disposability, design characteristics and accessories.

5. Indications for Use

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

6. Shelf life

Accelerated aging testing was performed to substantiate an expiration date of 5 years.

7. Biocompatibility testing

The “THD disposable Anoscope/Proctoscope” devices are compliant to the requirements of the ISO10993 standard.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

APR - 9 2008

THD Spa
% Mr. Guido Bonapace
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Via Calindri 50
40068 - San Lazzaro di Savena (BO)
ITALY

Re: K080132

Trade/Device Name: Family of "THD disposable Anoscope/Proctoscope"
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FER and GCF
Dated: January 14, 2008
Received: January 18, 2008

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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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.



Protecting and Promoting Public Health

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); 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.

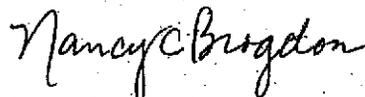
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,



Nancy C. Brogdon
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): K080132

Device Name: Family of "THD disposable Anoscope/Proctoscope"

Indications for Use:

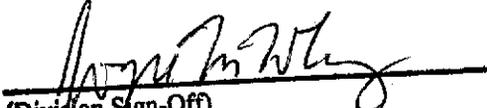
The family of "THD disposable Anoscope/Proctoscope" is intended for physician use to examine the anal sphincter, anus, rectum, and, using additional accessories, to perform various diagnostic and therapeutic procedures.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

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(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
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