DEC 1 1 2013

510(k) Summary for the

Family of disposable THD N-ano anoscope

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.
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Summary Preparation Date: October 29, 2013

2.2. Names

Device Name: THD N-ano anoscope
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, Rectoscopes and Light-scope	K103647

The THD N-ano anoscope and its predicate device are indicated for the same intended use and have the same technological characteristics. Both families include the anoscopes and similar devices manufactured with the same materials and the same process.

The differences between the families are that:

- The handle of THD N-ano anoscope is modified in order to lodge all the components of LED light source circuit (even though the LED light source circuit is not modified respect to predicate devices)
- As a consequence of the point above the LED light source block, used in predicate devices to lodge all the components of LED light source circuit, is eliminated
- The cover of the LED light source circuit of THD N-Ano anoscope is made of ABS Terluran, while the LED light source block of predicate devices is made of ABS Lustran.
- The THD N-Ano has similar dimensions than its predicate devices, but this doesn't include any change on safety and performances of the device, since the THD N-Ano measures are not more critical than dimensions of predicate devices. In fact length of THD N-ano anoscope is 105 mm, longer than an anoscope (which is 90 mm) but shorter than proctoscope (which is 130 mm)., while diameter is 21,7 mm, which is tighter than a Medium Anoscope/proctoscope (which is 22,1 mm, but there are also Large Anoscopes/proctoscopes with a diameter of 26,1 mm) and larger than a Pediatric – small size anoscope (which is 15,1 mm)
- The white polypropylene tip on the introducer, used in predicate devices is eliminated.

2.4. Device Description

The disposable, not sterile THD N-ano anoscope is a disposable, not sterile anoscope with an integrated LED light source.
The device is designed for the examination o the anal sphincter, anus, rectum to perform various diagnostic and therapeutic procedures.

The light source is integrated on the handle.

Differently than predicate devices (Family of THD disposable Anoscopes, Proctoscopes, Rectoscopes and Light-scope - K103647) disposable, not sterile THD N-ano Anoscope does not have any accessory and is available only "not sterile"

2.5. Indications for Use

The THD N-Ano Anoscope, is intended for physician use to examine the anal sphincter, anus, rectum to perform various diagnostic and therapeutic procedures.

The Indications for Use of THD N-Ano Anoscope have not been modified with respect to the previous submission (Family of THD disposable Anoscopes, Proctoscopes, Rectoscopes and Light-scope K103647).

2.6. Design Control Activities

As listed in chapter 2.3 the differences between THD N-Ano anoscpe and its predicate devices are:

- The handle of THD N-ano anoscope is modified in order to lodge all the components of LED light source circuit (even though the LED Light source is not modified respect to predicate devices)
- As a consequence of the point above the LED light source block, used in predicate devices to lodge all the components of LED light source circuit, is eliminated
- The cover of the LED light source circuit of THD N-Ano anoscope is made of ABS Terluran, while the LED light source block of predicate devices is made of ABS Lustran.
- The THD N-Ano has similar dimensions than its predicate devices, but this doesn't include any change on safety and performances of the device, since the THD N-Ano measures are not more critical than dimensions of predicate devices. In fact length of THD N-ano Anoscope is 105 mm, longer than an anoscope (which is 90 mm) but shorter than proctoscope (which is 130 mm)., while diameter is 21,7 mm, which is tighter than a Medium Anoscope/proctoscope (which is 22,1 mm, but there are also Large Anoscopes/proctoscopes with a diameter of 26,1 mm) and larger than a Pediatric – small size anoscope (which is 15,1 mm)
- The white polypropylene tip on the introducer, used in predicate devices is eliminated.

The summary about design review is described in the Annex 4.1. The summary about design review activity(Annex 4.1 – summary design review) relates the modification introduced with the risk analysis assessment (Annex 4.2 – Hazard analysis table).

The risk analysis method used to assess the impact of the modifications is described in the Annex 4.3 - Risk management plan.

A declaration of conformity with design controls is included in annex 1.1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 11, 2013

THD S.p.A.
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Imola (BO), Italy 40026

Re: K133687
Trade/Device Name: THD N-Ano Anoscope
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FER, GCP
Dated: October 29, 2013
Received: December 2, 2013

Dear Guido 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 contact 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. 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 -S

for

Benjamin R. Fisher, Ph.D.
Director
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): K133687

Device Name: THD N-Ano Anoscope

Indications for Use:

The THD N-Ano Anoscopes, are intended for physician use to examine the anal sphincter, anus, rectum 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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S
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