

K 090009

THD S.p.A.
SPECIAL 510(K) Notification

THD Slide One

510(k) Summary for the THD Slide

JAN 28 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.
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Italy

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Summary Preparation Date: December 15, 2008

2.2. Names

Device Name: THD Slide One
Classification Name: Nonfetal Ultrasonic monitor
Product Code: JAF
Regulation number: 892.1540

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.	THD Slide	K081429

2.4. Device Description

The THD Slide One consists of the THD Evolution Doppler device and the THD Slide One Kit. The THD Evolution Doppler device is an 8 MHz continuous wave (CW) Doppler detector with loudspeaker and a power light source. The THD Evolution Doppler is used with dedicated accessories (Doppler transducer, optical fibers and pneumatic foot pedal), in order to facilitate surgical operation. The THD Slide One Kit is a sterilized surgical kit comprised of a proctoscope, needle holder, knot tightener, sutures and Doppler probe. The kits used for the surgical treatment could be the THD Slide One kit or one of the kits already cleared by THD/G.F.; the THD kit that was included in the THD Submission (K070815) or the THD Slide (K081429)

2.5. Indications for Use

The THD Slide One Doppler guided proctoscope is a system for the surgical treatment of the hemorrhoids of second and third degree. It is based on Transanal Hemorrhoidal Dearterialization technique guided by a Doppler probe. The Doppler system, placed inside the THD Evolution Doppler device, is used to detect the terminal branch of the superior hemorrhoid artery, in order to perform ligation with a proctoscope, sutures and a needle holder included in the THD Kits.

The THD Slide One is to be used by physicians in hospitals, clinics, and physician's offices by prescription or doctor's orders.



JAN 28 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

THD Spa
% O'Connell Regulatory Consultants, Inc.
Ms. Maureen O'Connell
5 Timber Lane
North Reading, Massachusetts 01864

Re: K090009
Trade/Device Name: THD Slide One
Regulation Number: 21 CFR 892.1540
Regulation Name: Nonfetal ultrasonic monitor
Regulatory Class: II
Product Code: JAF
Dated: December 15, 2008
Received: January 2, 2009

Dear Ms. O'Connell:

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 (PMA), 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.

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 (240) 276-0115. 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,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 090009

Device Name: THD Slide One

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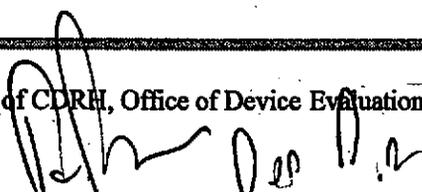
Prescription Use X
(Part 21 CFR 801 Subpart D)

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 General, Restorative,
and Neurological Devices

CONFIDENTIAL

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