

K081429

JUL 30 2008

### 510(k) Summary for the THD Slide

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:

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Summary Preparation Date:

May 16, 2008

#### 2.2. Names

Device Name:

THD Slide

Classification Name:

Nonfetal Ultrasonic monitor

Product Code:

JAF

Regulation number:

892.1540

#### 2.3. Predicate Devices

The THD Slide is substantially equivalent to the following device:

<i>Applicant</i>	<i>Device name</i>	<i>510(k) Number</i>
G.F. SRL	THD	K070815

## 2.4. Device Description

The THD Slide consists of the THD Evolution Doppler device and the THD Slide Kit. The THD Evolution Doppler 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 Kit is a sterilized surgical kit comprised of a proctoscope, a needle holder, a knot tightener and sutures.

## 2.5. Indications for Use

The THD Slide 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 THD Slide proctoscope, sutures and a needle holder included in the THD Slide Kit.

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

## 2.6. Performance Data

THD Ev. doppler Probe Id.	MI	$I_{spta_3}$ (mW/cm <sup>2</sup> )	Beam Area (mm <sup>2</sup> )	$W_0$ (mW)
Mean value:	0.027	232	3.063	15.633
Standard Dev.	0.0042	78	0.724	2.676
Max Value:	0.032	322	3.880	18.500

Performance data was submitted which shows that the acoustic emissions for the THD Slide are below the upper limits recommended by the guidance "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" September 30, 1997.



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

JUL 30 2008

Re: K081429  
Trade/Device Name: THD Slide  
Regulation Number: 21 CFR 892.1540  
Regulation Name: Nonfetal ultrasonic monitor  
Regulatory Class: II  
Product Code: JAF  
Dated: May 16, 2008  
Received: May 21, 2008

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

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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): K081429

Device Name: THD Slide

Indications for Use:

The THD Slide 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 THD Slide proctoscope, sutures and a needle holder included in the THD Slide Kit.

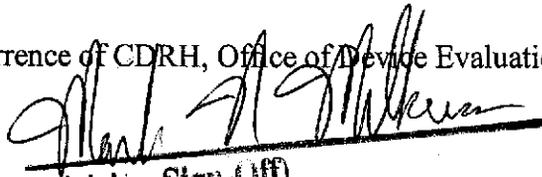
The THD Slide is to be used by physicians in hospitals, clinics, and physician's offices by prescription or doctor's orders.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of General, Restorative,  
and Neurological Devices

Appendix F

**Diagnostic Ultrasound Indications for Use Form**

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal					X					
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: THD Slide includes THD Evolution Doppler device with 8MHz Doppler probe

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

*Mark A. Miller*  
**(Division Sign-Off)**  
**Division of General, Restorative,**  
**and Neurological Devices**

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