JUN 2 0 2007

K 070815

510(k) Summary of Safety and Effectiveness for the THD

This 510(k) Summary of Safety and Effectiveness 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: March 20, 2007

2.2. Names

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

2.3. Predicate Devices

The THD is substantially equivalent to the following devices:

Applicant	*Device name*	*510(k) Number*
DWL-Electronische Systeme GmbH	HEMO-DOP	K041915
Multigon Industries, Inc.	DOPPLER GUIDED PROCTOSCOPE Model 500H	K052067

2.4. Device Description

The THD consists of the THD Evolution Doppler Device and the THD Kit. The THD Evolution Doppler is a 8 MHz continuous wave (CW) Doppler detector with loudspeaker and a power light source. The THD Evolution Doppler must be 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, sutures, a needle holder and a knot tightener.

2.5. Indications for Use

The THD Evolution 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 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 Kit.

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

2.6. Performance Data

The Acoustic output parameters measured for the THD Evolution are:

	MI	$Ispta_3$ (mW/cm^2)	Wo (mW)
Mean value:	0.027	232	15,633
Standard Dev:	0.0042	78	2,676
Max Value:	0.032	322	18,500

The results summarized in the table show that the THD Evolution is substantially equivalent in regards to acoustic performance to other devices legally marketed in United States and is below the upper limits recommended by the guidance "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" September 30, 1997.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

G.F. S.r.L..
% O'Connell Regulatory
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Ms. Maureen O'Connell
President
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North Reading, Massachusetts 01864

Re: K070815
Trade/Device Name: THD
Regulation Number: 21 CFR 892.1540
Regulation Name: Nonfetal ultrasonic monitor
Regulatory Class: II
Product Code: JAF
Dated: May 24, 2007
Received: May 29, 2007

JUN 2 0 2007

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.

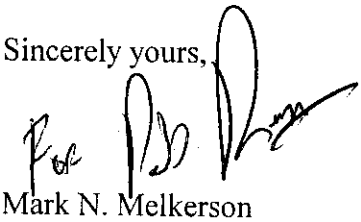
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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): K070815

Device Name: THD

Indications for Use:

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

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

510(k) Number K070815