K052067 12

AUG 2 9 2005

SUMMARY

This summary of 510k safety and effectiveness information is being submitted in accordance with 21CFR part 807.92

1. Submitters name, address, phone number, contact person and preparation date:

Name: Multigon Industries, Inc.
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Yonkers, N.Y. 10701
Phone: 914 376 5200 ext. 27
Fax: 914 376 6111
Email: wstern@multigon.com
Responsible person: William Stern

Official correspondent:
William Stern
Multigon Industries, Inc.
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Yonkers, N.Y. 10701
Phone: 914 376 5200 ext. 27
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Email: wstern@multigon.com

Date of Preparation:
7/1/05

2. Proprietary Name:
Model 500H Doppler Guided Proctoscope

Common /Usual Name:
Non Fetal Ultrasonic Monitor
Diagnostic Ultrasound Transducer

Classification Name:
21 CFR892.1540 Non Fetal Ultrasonic Monitor
21 CFR892.1570 Diagnostic Ultrasound Transducer

500H 510k Submission

500H Doppler Guided Proctoscope
Multigon Industries,Inc.

Classification Number:
90JAF
90ITX

3. Substantially Equivalent Devices

Multigon Industries, Inc. believes that the Model 500H Doppler Guided Proctoscope and Light source and transducers is substantially equivalent to the following cleared devices:

Trade or Proprietary Name	Manufacturer	510(k) Number
Model KM-25	Koven Technology Inc.	k951449
Hemo-Dop	DWL Elektronische Systeme,GmbH	k041915

The 500H includes Cuda Products Corp/ Sun Optics Light Source Model I-150 510k # k893491 and Cuda Products Corp/ Sunoptics fiber optic cable 510k# k901035 repackaged for convenience in the 500H.
The 500H includes a CW 8 mHz Doppler which is an updated version of the 8 mHz Doppler electronics module of the model Multigon Model 500A Vascular Spectrum Analyzer with CW Doppler 510k# k860435 which has been repackaged as the 8 mHz CW Doppler without the spectrum analyzer in the 500H for convenience. The 500H has the functionality only of producing the 8 mHz CW Doppler and insonating blood vessels. It enables the user to listen to the 8 mHz CW Doppler sound without any display, or calculation function.

Comparison of Multigon Model 500H Doppler Guided Proctoscope
and the two predicate devices cited above: Koven Technology, Inc. Model KM-25
and DWL Elektronische Systeme GmbH Hemo-Dop

500H	KM-25	Hemo-Dop
Uses 8mHz CW Doppler Sound to locate Hemorrhoidal artery	Same	Uses 8 mHz Pulsed Doppler to locate Haemorrrhoidal artery
8 mHz Doppler probe is removable	8 mHz Doppler probe is built into the proctoscope	8 mHz probe is built in to the proctoscope
Proctoscope is disposable	Proctoscope is not disposable	Proctoscope is not disposable

Proctoscope has fiber Optic illumination	Has incandescent bulb illumination built in scope	Has bulb illumination built in scope
Proctoscope has a port for hemorrhoidal artery ligation	Same	Same

4. DEVICE DESCRIPTION

The model 500H Doppler guided proctoscope consists of two parts . The first part is a Doppler probe in a proctoscope that are used integrally with each other and are not intended to be used separately. The Doppler guided proctoscope has a removable fiber optic light pipe, and a removable 8 mHz CW Doppler probe. The second part is a combination 8 mHz continuous wave (CW) Doppler detector with loudspeaker and a light source.

The Doppler guided proctoscope is inserted in the rectum and rotated until one of the branches of the hemorrhoidal artery is located. The artery is located when the user hears the classical arterial blood flow sound. The Doppler guided proctoscope is rotated such that the arterial sound is maximized thus insuring that the hemorrhoidal artery is under the Doppler probe and in the Doppler guided proctoscope's rectangular slit. The physcician or surgeon can then ligate the artery . The Doppler guided proctoscope is then rotated until the next hemorrhoidal artery branch is detected. The process is repeated until all detected hemorrhoidal arteries are located and ligated. After ligation the Doppler guided proctoscope can be rotated 360 degrees to make sure that all of the hemorrhoidal arterial branches have been ligated.

5. PERFORMANCE STANDARDS

No performance standards have been established for the 500H Doppler Guided Proctoscope under section 514 of the Federal Food and Drug Act. However the 500H Doppler Guided Proctoscope has been designed to meet the following standards:
UL 2601-1 Safety Requirements for Medical Equipment
AIUM/NEMA UD 2 Standard for Real Time Dsplay of Thermal and Mechanical Output Indices on Diagnostic Ultrasound Equipment
AIUM/NEMA UD 3 Standard for Real Time Display of Thermal and Mechanical Output Indices on Diagnostic Ultrasound Equipment
IEC 1157 Declaration of Acoustic Power
IEC60601-1-2
IEC60601-2-37

6. INDICATIONS FOR USE

The 500H is a Doppler guided proctoscope which is used to detect blood vessels supplying hemorrhoids and for performing HAL (Hemorrhoid Arterial Ligation) for Class II and Class III hemorrhoids. It is to be used by physicians in hospitals, clinics, and physicians offices by prescriptions or doctors orders.

7. CONTRA-INDICATIONS

None known at this time.

8. COMPARISON TO PREDICATE DEVICES

The 500H Doppler guided proctoscope has the same device characteristics as the approved predicate devices listed in item 3 above with the commonality of 8 mHz Doppler , principles of operation, and a Doppler guided proctoscope.

9. TEST DATA

The Model 500H Doppler guided proctoscope has been subjected to extensive safety, performance testing, and validation before release. Final testing of the 500H included various performance tests designed to ensure that the device met all of its functional specifications. Safety tests have been performed to ensure the device complies with applicable industry and safety standards.

The Model 500H Doppler guided proctoscope device labeling includes instructions for safe and effective use, warnings, cautions and guidance for use. It has therefore shown to be safe and effective.

10. ACOUSTIC OUTPUT

This is a summary table of the acoustic output of the 500H. The 500H acoustic output is below preamendment levels for vascular applications and is a Track 1 device.

Acoustic Output 500H

System: 500H

Probes: 8 mHz (center frequency 7.98 mHz)

Three probes were tested.

	MI	Ispta.3 (mW/cm squared)
Mean value	.0075	13.5
Std. Dev. (Sx)	0.0003	1.3
Limit(X)	0.089	19.1

11. SOFTWARE

The 500H has no software or firmware associated with it.

12. LITERATURE REVIEW

A review of the literature pertaining to the safety of the 500H Doppler guided proctoscope has been conducted and appropriate safeguards have been incorporated in the design of the 500H Doppler guided proctoscope.

13. CONCLUSIONS

The conclusion drawn from these tests is that the 500H Doppler guided proctoscope with an 8 mHz CW Doppler transducer is substantially equivalent in safety and efficacy to the predicate devices listed in item 3 above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 29 2005

Mr. William Stern
Official Correspondent
Multigon Industries, Inc.
1 Odell Plaza
YONKERS NY 10701

Re: K052067
Trade Name: Model 500H Doppler Guided Proctoscope
Regulation Number: 21 CFR 892.1540
Regulation Name: Nonfetal ultrasound monitor
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: JAF and ITX
Dated: July 28, 2005
Received: August 3, 2005

Dear Mr. Stern:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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). 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.

This determination of substantial equivalence applies to the following transducers intended for use with the Model 500H Doppler Guided Proctoscope, as described in your premarket notification:

Transducer Model Number

8 MHz Transducer Model 5008

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 determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your 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 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) 276-0120. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Mr. Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): K052067

Device Name: Model 500H Doppler Guided Proctoscope

Indications For Use: The Model 500H Doppler Guided Proctoscope is used to detect blood vessels supplying hemorrhoids and for performing HAL (Hemorrhoid Arterial Ligation) for Class II and Class III hemorrhoids. It is to be used by physicians in hospitals, clinics, and physician's offices by prescriptions or doctor's orders.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052067

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										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular					N					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: 8 MHz Transducer Model 5008 for the Model 500H Doppler Guided Proctoscope

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052067

Prescription Use (Per 21 CFR 801.109)