K041915

Written by:	GW / EM
Date:	13-04-2004

510K Summary

1. Identifying Information

Manufacturer: DWL Elektronische Systeme GmbH
Address: Josef-Schuettler Str. 2
D-78224 Singen
Germany
Telephone: +49 7731 79769 0
Fax: +49 7731 79769 99
E-Mail: info@dwl.de

Contact : Gerold Widenhorn / Regulatory Affairs

Name of Device : Hemo-Dop®

2. Class and Predicate Information

Classification Name: Ultrasonic pulsed Doppler imaging system 892.1550

Common Name: Ultrasound Doppler System

Proprietary Name: Hemo-Dop®

Class: Regulatory Class II

Predicate Device:

KOVEN TECHNOLOGY INC.; Model KM-25	K951449
DWL Elektronische Systeme GmbH; Multi-Dop® L	K930458

3. Performance Standards

Performance Standards: None
Conforms to the following voluntary standards: EN60601-1, EN60601-1-1, EN60601-1-2

4. Indications for Use

The Hemo-Dop® is a medical device to detect blood vessels supplying haemorrhoids and the subsequent HAL for haemorrhoids of state II and III. It can also be used as useful supplement when doing sclero-therapy and Barron ligature. Using the 8 MHz pencil probe it can be used for measuring the blood flow velocities in arteries and veins subcutaneous.

5. Device Description

The Hemo-Dop® consists of two parts. A proctoscope with implemented ultrasound probe and a basic unit which processes and displays the ultrasound signals. The proctoscope is inserted in the rectum of the patient. By turning the proctoscope, the whole circumference of 360° can be insonated. When the

© Copyright DWL Elektronische Systeme GmbH - Nur für von DWL autorisierte Personen!
Zuständigkeiten: V = Verantwortung, M = Mitwirkung, I = Information - Status: E = Entwurf, F = Freigegeben, U = Ungültig
Ausdruck vom: 23.04.2004 - Ursprungsdokument: V-QM-Doku-Hochformat-rev7.doc

ultrasound radiation meets a blood vessel, the frequency shift can be heard and it is graphically displayed. With the built-in 8 MHz pw/cw probe one can measure in different depths that means that the user not only knows the exact position of the vessel but also the depth in which it flows. Through the proctoscope the user can legate the vessel. Since this takes place in the area behind the linear dentate the patient doesn't need a general or local anaesthesia and can be treated as outpatient. An 8 MHz pencil probe is available as an option which enables the quick and reliable evaluation of the blood flow signals of the extracranial and peripheral vessels.

6. General Safety and Effectiveness

The Hemo-Dop® is similar to currently distributed pulsed Doppler ultrasound systems with proctoscope including 8MHz probe and 8MHz pencil probe. The Doppler signal is displayed in a FFT. Maximum acoustic output level is under by the FDA recommended limit and power level is displayed all the time.

Following acoustic output parameters have been measured

✍ 8MHz Pencil Probe PW mode

	Max Value	Power [mW]	f_c [MHz]	Z_{SP} [cm]	X_6, Y_6 [cm]	PD [µs]	PRF [Hz]	EBD Az,Ele [cm,cm]
$I_{SPTA.3}$ (mW/cm²)	334	10.2	7.82	0.7	0.168,0.148	-	-	0.5,0.25
$I_{SPPA.3}$ (W/cm²)	1.86	10.2	7.82	0.7	0.168,0.148	20	9000	-

✍ Proctoscope Probe PW mode

	Max Value	Power [mW]	f_c [MHz]	Z_{SP} [cm]	X_6, Y_6 [cm]	PD [µs]	PRF [Hz]	EBD Az,Ele [cm,cm]
$I_{SPTA.3}$ (mW/cm²)	8.1	0.74	7.88	0.65	0.428,0.272	-	-	0.3,0.5
$I_{SPPA.3}$ (W/cm²)	0.04	0.74	7.88	0.65	0.428,0.272	20	9000	-

7. Patient Contact Material

The material of the proctoscope which comes in contact with patient is:

Ligateur Tube	PMP	(USP class VI)
Ligateur Body and Handle	PPSU black	(USP class VI)
Epoxy Glue	EP42HT	(USP class VI)
Glue	Photobond 4442	(USP class VI)

The material of the Pencil probes which comes in contact with patient is:

Lens	San	(USP class VI)
Housing	ABS	(USP class VI)
Epoxy Glue	EP42HT	(USP class VI)

8. Software

The Hemo-Dop® operating system is MS-Dos.

9. Conclusion

In accordance with the FDA and based on the information provided in this Premarket notification, DWL Elektronische Systeme GmbH concludes that the Hemo-Dop is safe and effective and substantially equivalent to predicate devices described herein.

© Copyright DWL Elektronische Systeme GmbH - Nur für von DWL autorisierte Personen!
Zuständigkeiten: V = Verantwortung, M = Mitwirkung, I = Information - Status: E = Entwurf, F = Freigegeben, U = Ungültig
Ausdruck vom: 23.04.2004 - Ursprungsdokument: V-QM-Doku-Hochformat.rev7

Written by:	GW / EM
Date:	12-07-2004

Indication of Use

The Hemo-Dop® is a medical device to detect blood vessels supplying haemorrhoids and the subsequent HAL for haemorrhoids of state II and III. It can also be used as useful supplement when doing sclero-therapy and Barron ligature. Using the 8 MHz pencil probe it can be used for measuring the blood flow velocities in arteries and veins subcutaneously.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

© Copyright DWL Elektronische Systeme GmbH - Nur für von DWL autorisierte Personen!
Zuständigkeiten: V = Verantwortung, M = Mitwirkung, I = Information - Status: E = Entwurf, F = Freigegeben, U = Ungültig
Ausdruck vom: 12.07.2004 - Ursprungsdokument: V-QM-Doku-Hochformat-rev7.doc

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 4 2004

DWL Elektronische Systeme GmbH
% Mr. Stefan Preiss
Responsible Third Party Official
TÜV Product Service
1775 Old Highway 8
NEW BRIGHTON MN 55112-1891

Re: K041915
Trade Name: Hemo-Dop[R] System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: 90 IYN and ITX
Dated: July 14, 2004
Received: July 16, 2004

Dear Mr. Preiss:

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 Hemo-Dop[R] System, as described in your premarket notification:

Transducer Model Number

8 MHz PW/CW (Proctoscope)
8MHz Pencil Probe

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 (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact 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)

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

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

Additional Comments: Hemo-Dop® System

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041915

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				N	N					
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: Proctoscope with inbuild 8 MHz Transducer

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K041915

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				P	P					
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 Pencil Probe

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K041915