K030466

SEP 1 2 2003

510(k) Summary

As Required by 21 section 807.92 (c)

1-Submitter Name: Elcat GmbH

2-Address: Schießstättstraße 29
D-82515 Wolfratshausen
Germany

3-Phone: 011 49 8171 4214-0

4-Fax: 011 49 8171 4214-47

5-Contact Person: Mr Bernd Marquardt (General Manager)

6-Date summary prepared: January 30th, 2003

7- Official Correspondent: Mansour Consulting LLC

8- Address: 1308 Morningside Park Dr
Alpharetta, GA 30022 USA

9- Phone: (770) 908-8180

10- Fax: (425) 795-9341

11- Contact person: Jay Mansour, president

12-Device Trade or Proprietary Name: HANDYDOP

13-Device Common or usual name: Doppler

14-Device Classification Name: MONITOR, ULTRASONIC, FETAL

15-Substantial Equivalency is claimed against the following device:

Medasonics' Cadence Doppler Ultrasound System, 510k #k991441 (refer to Appendix 2 for FDA website printout)

This notification for HANDYDOP is of the ABBREVIATED type as per the declaration of conformity included in this summary

16-Description of the Device:

The Handydop is a handheld, unidirectional, continuous wave (CW) Doppler with three changeable probes. 2MHz CW probe for foetal heartbeat detection, 4MHz CW probe and 8 MHz CW probe for peripheral vascular applications. You can hear the blood flow from a vein as a modulated noise on the speaker of the handydop. The Handydop works cordless with two 9V Battery's or Accumulators. The housings of the Handydop and the probes are made of ABS-plastics. The quartz crystals where encapsulated with Araldit-D (a Duroplastic). As control panel there are only the ON/OFF switch and the loudness wheel.

17-Intended use of the device: *(Indications for use typed on a separate FDA form)*

HandyDop™ is a device designed to transmit and receive ultrasonic energy into and from the pregnant woman, by means of continuous wave (doppler) echoscopy. The device is indicated for use to detect the flow of blood within the body.

When using it with the 2 MHz probe, HandyDop™ is indicated for use for the early detection of fetal life, detection of multiple pregnancies, fetal screening from early gestation through delivery, and general indication of fetal well being.

When using it with the 4 MHz or 8 MHz probes, HandyDop™ is indicated for use for detection of blood flow in the peripheral vascular system for assisting in the detection of peripheral vascular disease.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 12 2003

ELCAT Gmbh
% Mr. Jay Mansour
President
Mansour Consulting, LLC
1308 Morningside Park Dr.
ALPHARETTA GA 30022

Re: K030466
Trade Name: HandyDop™
Regulation Number: 21 CFR 884.2660
Regulation Name: Fetal ultrasonic monitor and accessories
Regulatory Class: II
Product Code: 85 KNG
Dated: July 23, 2003
Received: July 28, 2003

Dear Mr. Mansour:

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 HandyDop™, as described in your premarket notification:

Transducer Model Number

2MHz
4MHz
8MHz

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,

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

Enclosure

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					N					
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: HANDYDOP™ IS DESIGNED TO TRANSMIT AND RECEIVE ULTRASONIC ENERGY INTO & FROM THE RECIPIENT WOMAN BY MEANS OF CONTINUOUS WAVE (DOPPLER) ENERGY TO DETECT FLOW OF BLOOD WITHIN THE BODY

2 MHz PROBE IS FOR USE FOR EARLY DETECTION OF FETAL LIFE, DETECTION OF MULTIPLE PREGNANCIES, FETAL SCREENING FROM EARLY GESTATION THROUGH P.T.O

(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 K030466

PAGE 4

SUBJECT 510K # K030466

DATE 07/23/03

CONTINUATION OF COMMENTS

DELIVERY, AND GENERAL INDICATION OF FETAL WELL BEING.

4 MHz & 8 MHz PROBES ARE FOR USE FOR DETECTION OF BLOOD FLOW IN THE PERIPHERAL VASCULAR SYSTEM OF THE BODY FOR ASSISTING IN THE DETECTION OF PERIPHERAL VASCULAR DISEASE. <END>

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					N					
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
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: 2 MHz PROBE IS INDICATED FOR USE FOR THE EARLY DETECTION OF FETAL LIFE, DETECTION OF MULTIPLE PREGNANCIES, FETAL SCREENING FROM EARLY GESTATIONAL THROUGH DELIVERY, AND GENERAL INDICATION OF FETAL WELL BEING

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Legum

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K030466

Prescription Use (Per 21 CFR 801.109)

PAGE 6

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: 4 MHz PROBE IS INDICATED FOR USE FOR DETECTION of BLOOD FLOW IN THE PERIPHERAL VASCULAR SYSTEM of THE BODY FOR ASSISTING IN THE DETECTION of PERIPHERAL VASCULAR DISEASE

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K030466

Prescription Use (Per 21 CFR 801.109)

Page 7

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 PROBE IS INDICATED FOR USE FOR DETECTION of BLOOD FLOW IN THE PERIPHERAL VASCULAR SYSTEM of THE BODY for ASSISTING IN THE DETECTION of PERIPHERAL VASCULAR DISEASE

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K030466

Prescription Use (Per 21 CFR 801.109)