K060410

APR 7 2006

SAFETY AND EFFECTIVENESS SUMMARY
Summit Doppler Systems, Inc.
EchoHeart Transvaginal Doppler

Name and Address:

Summit Doppler Systems, Inc.
4620 Technology Dr. #100
Golden, CO 80403

Phone: (303) 423-7572
Fax: (303) 431-5994

Contact: Ken Jarrell – President

Preparation Date: February 10, 2006

Device Name: EchoHeart Transvaginal Doppler

Common Name: Transvaginal Doppler Probe

Classification:

Class II per:	FR Number	Product Code
Transducer, Ultrasonic, Diagnostic	892.1570	ITX

Indications for Use: This product will be used to detect fetal heart tones transvaginally as an aid for determining fetal viability.

Description: The EchoHeart Transvaginal Doppler is an interchangeable transvaginal Doppler probe used with the handheld LifeDop Doppler System. It is designed for more consistent determination of fetal viability in difficult examinations when a standard transabdominal probe is insufficient – such as early gestations, obese patients and retroverted uterine positions.

Substantial Equivalence: The EchoHeart Transvaginal Doppler probe is substantially equivalent to the currently marketed Summit Doppler LifeDop system w/ 3.2 MHz fetal probe and Atlantis Diagnostic International Transvaginal Probe.

Summit Doppler Systems, Inc.	Atlantis Diagnostics International, Inc.
Golden, Colorado	Bothell, WA 98011
LifeDop Doppler w/ 3MHz Probe	HDI 1000 Diagnostic w/ Transvaginal Probe
K024197, Cleared 1/3/03	K961073, Cleared 2/19/97

Technologies Summary: Doppler ultrasound technology is the same as substantially equivalent devices shown above.

Conclusion: Based on comparisons of device features, materials, intended use and performance, and user instructions, the LifeDop Doppler is shown to be substantially equivalent to the commercially available and legally marketed device indicated above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 7 2006

Mr. Ken Jarrell
President
Summit Doppler Systems, Inc.
4620 Technology Drive, Suite 100
GOLDEN CO 80403

Re: K060410
Trade Name: EchoHeart Transvaginal Doppler Probe
Regulation Number: 21 CFR 884.2660
Regulation Name: Fetal ultrasonic monitor and accessories
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: HEK and ITX
Dated: February 10, 2006
Received: February 16, 2006

Dear Mr. Jarrell:

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 EchoHeart Transvaginal Doppler Probe used with the LifeDop Doppler Ultrasound System, as described in your premarket notification.

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 Ewa Czerska, M.D. at (301) 594-1212.

Sincerely yours,

David C. Dyson

for 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

Main unit LifeDop system with EchoHeart Transvaginal Doppler probe
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					P, E					
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal					N					
Transurethal										
Intravascular										
Peripheral Vascular					P, E					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Previously cleared indication is K024197, issued 1/3/03

Additional Comments: The system consists of main unit plus an EchoHeart Transvaginal Probe
Only one transducer can be used with the main unit at a time.

(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 CRF 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K060440

Diagnostic Ultrasound Indications for Use Form

EchoHeart Transvaginal Probe
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					N					
Transurethal										
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: The above is for EchoHeart Transvaginal Doppler probe

(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 K060440

Prescription Use (Per 21 CRF 801.109)