DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 12 2004

Mr. Gregory C. Falk
American IV Products, Inc.
7485 Shipley Avenue
HANOVER MD 21076

Re: K040392
Trade/Device Name: Transducers for Ultrasound and Tocodynamometer Fetal Monitoring
Regulation Number: 21 CFR 884.2720
Regulation Name: External uterine contraction monitor and accessories
Regulation Number: 21 CFR 884.2960
Regulation Name: Obstetric ultrasonic transducer and accessories
Product Code: 85 HFM and HGL
Dated: July 8, 2004
Received: July 12, 2004

Dear Mr. Falk:

This letter corrects our substantially equivalent letter of September 14, 2004 regarding the transducers for ultrasound and tocodynamometer fetal monitoring. The letter listed only the ultrasound transducers (FM10835, FM10836) to which the determination of substantial equivalence applies. However, the determination of substantial equivalence applies to all five transducers described in your premarket notification, i.e. FM10835, FM10836, FM 10839, FM 10840, and FM 10841.

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 (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 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 continue 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 one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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) you may obtain. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

David A. Seymour

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

Enclosure

Indications for Use

510(k) Number (if known): K040392

Device Name: Transducers for Ultrasound and Tocodynamometer Fetal Monitoring

Indications For Use:

These devices are intended to be used as replacement accessories to Corometrics and Hewlett Packard Monitors, to measure fetal heart rate and uterine contractions in the gravid patient.

AIV Transducer Model Numbers: FM10835 and FM10836.
These devices are a direct replacement for the EPIC EFU200-20, Ultrasound Transducer for measuring fetal heart rate.

AIV Transducer Model Numbers: FM10839 and FM10840.
These devices are a direct replacement for the Corometric's 2264LAX, TOCO Transducer for measuring uterine contractions.

AIV Transducer Model Number: FM10841.
This device is a direct replacement for the EPIC EFT200-20, TOCO Transducer for measuring uterine contractions.

Required information for the ultrasound transducers, relating to their indications for use, is attached.

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)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040392

7485 Shipley Avenue • Hanover, MD • 21076 • USA • p 800.990.2911 • f 410.787.1337 • www.aiv-inc.com

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer

Intended Use: Diagnostic ultrasound imaging or fluid analysis of the human body as follows:

AIV Transducer Model Number: FM10835
Replacement for Epic Model Number EFU200-20 (also HP Model 1356)

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

Intended for use with Philips Medical (HP) M1350A and Viridia Series 50 XM monitors.

Additional Comments: This device is a direct replacement for the EPIC EFU200-20 (and Hewlett Packard Model 1356, by Epic Substantial Equivalence K992811) Ultrasound Transducer for measuring fetal heart rate.

David G. Lagomarsino

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040392

Prescription Use ✓

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer

Intended Use: Diagnostic ultrasound imaging or fluid analysis of the human body as follows:

AIV Transducer Model Number: FM10836
Replacement for Epic Model Number EFU200-20 (also HP Model 1356)

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

Intended for use with Philips Medical (HP) M1350A and Viridia Series 50 XM monitors.

Additional Comments: This device is a direct replacement for the EPIC EFU200-20 (and Hewlett Packard Model 1356, by Epic Substantial Equivalence K992811) Ultrasound Transducer for measuring fetal heart rate.

David A. Lagomarsino

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040392

Prescription Use ✓

SEP 1 4 2004

Supporting Clinical Engineering Worldwide

510(k) Summary (Ref:K040392)

Submitter Information:

American IV Products, Inc.
7485 Shipley Avenue
Hanover, MD 21076

Contact:

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Engineering Manager
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Date Prepared:

February 13, 2004

Product Name:

Classification Name: Perinatal Monitoring System Accessories
Common Name: Transducers for ultrasound and tocodynamometer fetal monitoring
Proprietary Name: Transducers for ultrasound and tocodynamometer fetal monitoring

List of Submitted Devices:

TOCO	Ultrasound
FM10839	**FM10835**
FM10840	**FM10836**
FM10841	

Predicate Device:

These AIV devices are equivalent to the following legally marketed devices:

Corometrics Models
2264LAX (TOCO) K982651
5700LAX (Ultrasound) K982651

Epic Models
EFT200-20 (TOCO) K992811
EFU200-20 (Ultrasound) K992811

Hewlett Packard Models
1355 TOCO) (by Epic equivalence reference K992811)
1356 (Ultrasound) (by Epic equivalence reference K992811)

Description:

AIV's ultrasound (US) and tocodynamometer (TOCO) transducers are replacements for similar transducers manufactured by Corometrics and Hewlett Packard for their respective monitors. The AIV transducers are also a replacement for similar transducers manufactured by Epic for use on Corometrics and Hewlett Packard monitors.

The US transducers are used to detect the fetal heart rate using Doppler shift technology. The TOCO transducers detect uterine activity using a strain gauge for evaluating contractions. These transducers are intended to be a direct replacement for the Corometrics, Hewlett Packard and Epic transducers.

Intended Use:

These devices are intended to be used as replacement transducer accessories for Corometrics and Hewlett Packard monitors, for use in measuring fetal heart rates and uterine contractions.

Comparison to Predicate Device:

	AIV	**Corometrics**	**Epic**
Intended Use	Measure fetal heart rate and uterine contractions in the gravid patient.	Same	Same
Anatomical Sites	The ultrasound transducer is placed on the maternal abdomen aimed at the fetal heart; the TOCO transducer is placed on the maternal abdomen over the fundal area of the uterus.	Same	Same
Target Patient Population	Gravid patients, especially during labor.	Same	Same
FHR Range	Dependent upon monitor specifications.	Same	Same
Uterine Activity Range	Dependent upon monitor specifications.	Same	Same
Patient Use/Reuse	Reusable.	Same	Same
Sterility	Non-sterile	Same	Same
Description of Patient Attachment	These devices attach to the gravid patient with elastic straps around the waist.	Same	Same
Cable Length	10 feet		8 feet
Accessories	Transducer belts and ultrasonic gel	Same	Same
Connector Design	Transducer cable connectors are color-coded and keyed to fit the appropriate fetal monitors.	Same	Same
Acoustic Output	<20mW/cm^2 average	Same	Same
Operational Characteristics	AIV FM10835 = Pulsed Doppler AIV FM10836 = Pulsed Doppler	5700LAX = Pulsed Doppler	EFU200-20 = Pulsed Doppler
Specifications (Ultrasound Center Frequency)	AIV FM10835 = 1.0 MHz AIV FM10836 = 1.0 MHz	5700LAX = 1.151 MHz	EFU200-20 = 1.0 MHz

Performance Data and Conclusions:

- Acoustic output testing shows power is less than 20mW/cm^2 average.
- AIV assembly design is equivalent to predicate device assembly design.
- Bench Testing demonstrates that the AIV devices perform as intended and are equivalent to predicate device assemblies.
- AIV plastics have conformed to consensus standards relating to Biocompatibility.
- These devices do not raise new issues of safety and effectiveness, nor do they alter the fundamental technology of the predicate devices.