AUG 16 2004

K040819

Supporting Clinical Engineering Worldwide

510(k) Summary

Submitter Information:

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

Contact:

Gregory Falk
Engineering Manager
Telephone: 410-787-1300 ext. 131
Fax:: 410-787-1337
e-mail: gfalk@aiv-inc.com

Date Prepared:

March 26, 2004

Product Name:

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

Predicate Device:

These AIV devices are equivalent to the following legally marketed devices:
Corometrics Models
5700LAX (Ultrasound) K982651

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. These transducers are intended to be a direct replacement for the Corometrics transducers.

Intended Use:

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

Comparison to Predicate Device:

	AIV	Corometrics
Intended Use	Measure fetal heart rate and uterine contractions in the gravid patient.	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
Target Patient Population	Gravid patients, especially during labor.	Same
FHR Range	Dependent upon monitor specifications.	Same
Uterine Activity Range	Dependent upon monitor specifications.	Same
Patient Use/Reuse	Reusable.	Same
Sterility	Non-sterile	Same
Description of Patient Attachment	These devices attach to the gravid patient with elastic straps around the waist.	Same
Cable Length	10 feet	
Accessories	Transducer belts and ultrasonic gel	Same
Connector Design	Transducer cable connectors are color-coded and keyed to fit the appropriate fetal monitors.	Same
Acoustic Output	<20mW/cm^2 average	Same
Operational Characteristics	AIV FM10833 = Pulsed Doppler AIV FM10834 = Pulsed Doppler AIV FM10835 = Pulsed Doppler	5700LAX = Pulsed Doppler
Specifications (Ultrasound Center Frequency)	AIV FM10833 = 1.151 MHz AIV FM10834 = 1.151 MHz AIV FM10835 = 1.0 MHz	5700LAX = 1.151 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 16 2004

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

Re: K040819
Trade/Device Name: Transducers for Ultrasound Fetal Monitoring
Regulation Number: 21 CFR 884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: 85 HGM
Dated: July 9, 2004
Received: July 12, 2004

Dear Mr. Falk:

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 application (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 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 letter will allow you to begin 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" (21CFR 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,

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

Indications for Use

510(k) Number (if known): K040819

Device Name: Transducers for Ultrasound Fetal Monitoring

Indications For Use:

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

AIV Transducer Model Numbers: FM10833 and FM10834.
These devices are direct replacements for the Corometric's 5700LAX.

Intended for use with Corometrics Fetal monitor models:
116,118,120 Series,150,151,155 and 340

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)

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040819