K992811 page 1/2

Epic Medical Equipment Services
1800 10TH STREET, SUITE 300, PLANO, TEXAS 75074

JAN 1 8 2000

510(k) Summary

Submitter Information:

Epic Medical Equipment Services, Inc.
1800 E. 10th Street, Suite 300
Plano, TX 75074

Contact:

Krista Oakes
Vice President, Regulatory Affairs and Quality Assurance
Telephone: (972) 801-9854
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Date Prepared:

August 17, 1999

Product Name:

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

Predicate Device:

These devices are equivalent to the following legally-marketed devices:
Corometrics Models
FM (US & TOCO)
115 (5600 & 2260) – K843385
116 (5700 & 2260) – K891595
118 (5700 & 2260) – K934959
120 (5700 & 2260) – K964770

Hewlett Packard Models
8040 (15245 & 15248) – 510(k) unknown
1350 (1356 & 1355) – K900480

Description:

Epic's ultrasound and tocodynamometer (toco) transducers are replacements for similar transducers manufactured by Corometrics and Hewlett Packard for their respective monitors. The ultrasound transducers are used to detect the fetal heart rate using Doppler shift technology and the toco transducers detect uterine activity using a strain gauge for evaluating the fetal heart rate during a contraction. These transducers are intended to be a direct replacement for the OEM 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 rate and uterine contractions.

Comparison to Predicate Device:

	Epic	**Corometrics**	**Hewlett Packard**
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 and 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 patient with elastic straps around the mother.	Same	Same
Cable length	8 feet	Same	Same
Accessories	Transducer Belts and Ultrasonic Gel	Same	Same
Connector design	Transducer connectors are color- coded and keyed to fit into the appropriate fetal monitors.	Same	Same
Acoustic output	$< 20 mW/cm^2$ ave.	Same	Same
Operational Characteristics	EFU100-20 = Pulsed Doppler EFU200-20 = Pulsed Doppler EFU300-25 = Continuous EFU400-25 = Pulsed Doppler	Coro 5600 = Continuous Coro 5700 = Pulsed Doppler	HP 8040 = Pulsed Doppler HP 1356 = Pulsed Doppler
Specifications (Ultrasound Center Frequency)	Epic EFU100-20 = 1.0 MHz Epic EFU200-20 = 1.0 MHz Epic EFU300-25 = 2.3 MHz Epic EFU400-25 = 1.151 MHz	Corometrics 5600 = 2.3 MHz Corometrics 5700 = 1.151 MHz	HP 8040 = 1.024 MHz HP 1356 = 0.9984 MHz

Performance Data & Conclusions:

- Acoustic output testing shows $< 20 mW/cm^2$ avg.
- Bench testing demonstrates that the devices perform as intended.
- The company has declared conformity to consensus standards relating to Electrical/Mechanical/Thermal Safety and Biocompatibility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 8 2000

Ms. Krista Oakes
Vice President, Regulatory Affairs and
Quality Assurance
Epic Medical Equipment Services, Inc.
1800 10th Street, Suite 300
Plano, TX 75074

Re: K992811
Transducers for Ultrasound and
Tocodynamometer Fetal Monitoring
Dated: November 16, 1999
Received: November 29, 1999
Regulatory Class: II
21 CFR §884.2720/Procode: 85 HFM
21 CFR §884.2660/Procode: 85 HEL

Dear Ms. Oakes:

We have reviewed your Section 510(k) 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications For Use

510(k) # K992811
Device Name: Transducers for Ultrasound and Tocodynamometer Fetal Monitoring

Indications for Use:
These devices are intended for use as replacement accessories to Corometrics and Hewlett Packard Monitors, to measure fetal heart rate and uterine contractions in the gravid patient.

Required information relating to ultrasound transducer indications for use is attached.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-the-Counter Use _____

David A. Segraves
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K992811