SEP 1 1999

9.0 510(k) SUMMARY: Corometrics® Model 171/172 Fetal Monitor

Prepared: June 3, 1999

[807.92(a)1] Contact Information

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Regulatory Affairs Manager

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[807.92(a)2] Device Name and Classification

The proprietary name of the modified device to be introduced into interstate commerce is the Corometrics Model 171/172 Series Fetal Monitor. Common names include: Model 170 Series, Model 171/172 FM.

As with the predicate Corometrics Model 150 Fetal Monitor and the Corometrics Spectra 400 Extended Surveillance and Alert Systems, the Model 171/172 Series Fetal Monitor is a Class II device.

[807.92(a)3] Identification of Legally Marketed Equivalent Devices (Predicate Systems).

Predicate System	Manufacturer	K Number
Corometrics Model 150 Fetal Monitor	GE Marquette Medical Systems, Inc. 61 Barnes Park Road North	k920376, clearance date: 4/27/92
Corometrics Spectra 400 Extended Surveillance and Alert Systems	GE Marquette Medical Systems, Inc. 61 Barnes Park Road North	K852608, clearance date: 9/29/85

[807.92(a)4 & 807.92(a)5] Device Description & Intended Use

The Model 171/172 Series Fetal Monitor is intended for monitoring fetal and maternal vital signs: fetal heart rate and maternal uterine activity, fetal movement detection, and an interface for select maternal NIBP monitors. The device is intended for use in a hospital/clinical environment.

[807.92(a)6] Predicate Device Comparison of Technological Characteristics

Monitoring Mode	Model 150	Spectra 400	Model 171/172
Fetal Heart Rate Monitoring	Yes	Yes	Yes
Uterine Activity Monitoring	Yes	Yes	Yes
FMD detection upgrade kit (Option)	Yes	Can Display FMD	Yes
Hi/Low Fetal Heart Rate Notification	No	Yes	Yes

[807.92(b)1, 807.92(b)2 & 807.92(b)3] Performance Standards per the Food, Drug and Cosmetic Act

To date, no performance standards relating to devices of this type have been promulgated by the Food and Drug Administration.

[807.92(d)] Additional Information

The Model 171/172 Series Fetal Monitor has been extensively tested to meet its requirements and design.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 1999

Mr. Richard Cehovsky
Regulatory Affairs Manager
GE Marquette Medical Systems, Inc.
61 Barnes Park Road North
Wallingford, CT 06492

Re: K991905
Corometrics Model 171 and 172 Fetal Monitor
Dated: June 3, 1999
Received: June 4, 1999
Regulatory Class: II
21 CFR §884.2740/Procode: 85 HGM

Dear Mr. Cehovsky:

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

510(k) Number (if known): K991905 *

Device Name: Model 171/172 Series Fetal Monitor

Indications for Use:

I. Fetal Surveillance

The Corometrics® Model 171/172 Series Monitors are used for monitoring of the fetus during the antepartum period as well as throughout labor and delivery (i.e. fetal heart rate and uterine activity monitoring). The device also has an optional monitoring mode to detect fetal body movements.

II. Maternal NBP Recording

Blood Pressure. The monitor has an interface to select external NBP monitors. The Monitor does not process any NBP data but only prints the NBP data , from the external monitor, to its chart recorder.

* To be assigned by FDA upon receipt of 510(k) submission.

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

Concurrence if CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use ____
(Per 21 CFR 801.19)

Optional Format 1-2-96

David A. Segura
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991905