

AUG 19 1999

K991739 p1of2

Corometrics Model 120 Series Version 2.0
510(k) Premarket Notification
May 1999

10.0 510(k) SUMMARY: Corometrics 120 Series, Version 2.0

Prepared: May 1999

[807.92(a)1] Contact Information

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Sr. Regulatory Compliance Specialist

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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 120 Series Maternal/Fetal Monitor. Common names include: 120 Series, 120 MFM.

As with the predicate system, the 120 Series (i.e. Model 126, 128, 129 configurations) continue to be Class II devices.

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

Predicate System	Manufacturer	k Number
120 Series Maternal/ Fetal Monitor	GE Marquette Medical Systems, Inc 61 Barnes Park Road North Wallingford, CT 06492	k964770, SE: 2/21/97
Fetal Movement Detection		k955559, SE: 3/5/96
Spectra 400 Extended Surveillance and Alerts System		k852608, SE: 9/29/85

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

The 120 Series is intended for monitoring fetal and maternal vital signs: fetal heart rate; optional fetal movement detection, FHR and UA alarms, and maternal uterine activity, heart/pulse rate, blood pressure, and %SpO₂. The device is intended for use in a hospital/clinical environment.

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

Monitoring Mode	120 Series	Model 118	Model 556
FHR/UA Monitoring	Yes	Yes	Not Applicable
Maternal Heart/Pulse Rate, NBP, SpO ₂ Monitoring	Yes	Yes	
MECG Waveform	Yes	No	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 120 Series has been extensively tested to meet its requirements and design.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 19 1999

Ms. Maria Vitug Fouts
Senior Regulatory Compliance Specialist
GE Marquette Medical Systems, Inc.
200 Harry S. Truman Parkway, Suite 220
Annapolis, Maryland 21401

Re: K991739
Maternal/Fetal Monitor
Corometrics 120 Series, Version 2.0
Dated: May 20, 1999
Received: May 21 1999
Regulatory Class: II
21 CFR §884.2740/Procode: 85 HGM

Dear Ms. Fouts:

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 (Pre-market 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

May 1999

510(k) Number (if known): K991739 *

Device Name: 120 Series Maternal/Fetal Monitor

Indications for Use:

I. Fetal Surveillance

A Corometrics 120 Series Monitor is used for non-invasive and invasive monitoring of the fetus during the antepartum period as well as throughout labor and delivery (i.e. fetal heart rate and uterine activity monitoring). Fetal movement detection and fetal heart rate alarm options (user selectable high/low and poor signal quality alarms or Spectra alerts) are available.

II. Maternal Monitoring

A Corometrics 120 Series Monitor is intended for monitoring maternal vital signs to help assess maternal well-being. The vital signs which can be measured with these monitor configurations are summarized below.

NOTE: Maternal vital signs provided by the monitor should only be used as an adjunct in patient assessment in conjunction with clinical signs and symptoms.

Blood Pressure. The monitor is intended for use in the non-invasive monitoring of maternal blood pressure (NBP). This monitor is not intended for use in neonatal or pediatric blood pressure monitoring.

Pulse Oximetry. The monitor is intended for use in the non-invasive monitoring of maternal functional oxygen saturation of arterial hemoglobin (MSpO₂).

Heart/Pulse Rate. The monitor is intended for use in the non-invasive monitoring of the maternal heart/pulse rate. Additionally, a MEKG waveform "snapshot" may be displayed and printed.

NOTE: Only the maximum configuration provides both maternal heart rate and pulse rate data.

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

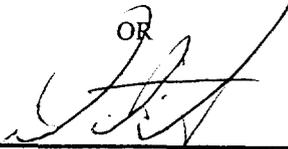
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Concurrence if CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.19)

Over the Counter Use

Optional Format 1-2-96

OR

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991739