NOV 1 3 2001

10.0 510(k) Summary: 120*is* Maternal/Fetal Monitoring System

K012718

Prepared: August, 2001

[807.92(a)1] Contact Information

Joelle Neider
Regulatory Affairs Specialist

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61 Barnes Park Road North
Wallingford, CT 06492

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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 120*is* Maternal/Fetal Monitor. Common names include: 120*is* Maternal/Fetal Monitoring System, Model 120*is*, and 120*is*.

As with the predicate system, the 120*is* Series (i.e. Model 126*is*, 128*is*, 129*is* 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 Medical Systems *Information Technologies* 61 Barnes Park Road North Wallingford, CT 06492	k964770, SE: 2/21/97
QS System	GE Medical Systems *Information Technologies* 445 Defense Highway Annapolis, MD 21401	k993008 SE: 12/6/99

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

The Corometrics Model 120*is* Maternal/Fetal Monitor 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 %$Sp0_2$. The device is intended for use in a hospital/clinical environment.

0078

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

120*is* Monitoring Mode	120 Series	QS
FHR/UA Monitoring	X	
Maternal Heart/Pulse Rate, NBP, SpO_2 Monitoring	X	
MECG Waveform	X	
Fetal movement detection	X	
Surveillance mode		X

[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

At the time of this submission, the Model 120*is* is undergoing extensive testing to ensure that it meets its requirements and design.

0079

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 3 2001

Ms. Joelle Neider
Corporate Regulatory Affairs
GE Medical Systems
General Electric Company
61 Barnes Park Road North
P.O. Box 333
WALLINGFORD CT 06492-0333

Re: K012718
Trade/Device Name: Model 120*is* Maternal/Fetal Monitoring System
Regulation Number: 21 CFR 884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: 85 HGM
Dated: August 13, 2001
Received: August 15, 2001

Dear Ms. Neider:

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 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.

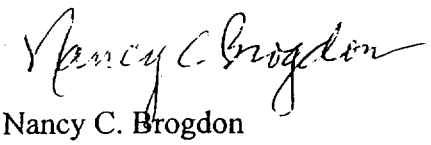
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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 this 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). 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
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

NOV 1 3 2001

K012718

510(k) Number (if known): K012718

Device Name: Corometrics Model 120*is* Maternal/Fetal Monitoring System

Indications For Use:

I. Fetal Surveillance

A Corometrics 120*is* Maternal/Fetal Monitoring System 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) are available.

II Maternal Monitoring

A Corometrics 120*is* Maternal/Fetal Monitoring System 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 as follows:

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 the 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, an MECG waveform "snapshot" may be displayed and printed.

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

Bed-to-bed surveillance is available when 120*is* Series Monitors are networked together

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012718

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)