K983795

AUG 12 1999

510(k) Summary
for
Analogic Corporation
Modifications to Fetalgard 3000 Fetal Monitor

DATE THIS SUMMARY WAS PREPARED: September 11, 1998

SUBMITTER'S NAME AND ADDRESS:

Analogic Corporation
8 Centennial Drive
Peabody, MA 01960

CONTACT PERSON:

Steven Clarke, Regulatory Specialist
Telephone (978)977-3000 extension 2388
Facsimile (781)245-1274

DEVICE NAME:

Proprietary Name: Fetalgard 3000 Fetal Monitor (Modification to)
Common Name: Perinatal Monitoring System
Classification Name: Perinatal Monitoring System and Accessories

PREDICATE DEVICE:

The legally marketed device to which equivalence is being claimed is:

Fetalgard 3000 Fetal Monitor

DEVICE DESCRIPTION:

The Fetalgard 3000 Fetal Monitor is a Perinatal Monitoring System for showing graphically the relationship between maternal labor and the fetal heart rate by means of combining and coordinating display of uterine contraction and fetal heart rate measurements.

Uterine contractions are monitored using an external tocotonometer or an intrauterine pressure transducer.

Fetal heart rate is measured using an external pulsed Doppler ultrasound transducer or directly with a spiral scalp electrode.

Maternal heart rate and respiration are measured using standard ECG electrodes.

Heart rate, respiration rate, and uterine activity are presented graphically on an LCD display or chart recorder and digitally on LED displays.

INTENDED USE:

The Fetalgard 3000 Fetal Monitor is a Perinatal Monitoring System for showing graphically the relationship between maternal labor and the fetal heart rate by means of combining and coordinating display of uterine contraction and fetal heart rate measurements. This data is intended to aid in assessing the well-being of the fetus during pregnancy (antepartum), and labor and delivery (intrapartum). The modifications described in this submission do not implement any changes in intended use.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

The modified Fetalgard 3000 Fetal Monitor is nearly identical to the predicate Fetalgard 3000 Fetal Monitor which was cleared for marketing under Premarket Notification K950420.

The tocotonometer has been redesigned using the same principle of operation, with changes in the design details to enhance reliability and improve ease of manufacture.

The top housing of the ultrasound transducer will be manufactured out of a different material, which is equivalent in terms of mechanical properties and biocompatibility.

The system software has undergone several evolutionary revisions to improve the detection and display of fetal heart rate under adverse conditions.

NONCLINICAL TESTS USED IN DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

The modifications to the device have undergone a subset of the original verification and validation test scenarios to show that all functions that may have been affected by the modifications are still in compliance with the original user requirements, and that safety and performance have not been adversely affected. This involved the use of both simulated input signals and tape recordings of actual physiological waveforms.

CONCLUSIONS FROM NONCLINICAL TESTING:

The testing of the modified Fetalgard 3000 Fetal Monitor demonstrates the performance is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 12 1999

Mr. Steven A. Clarke, RAC
Regulatory Affairs Manager
Analogic Corporation
8 Centennial Drive
Peabody, MA 01960

Re: K983395
Fetalguard 3000 Fetal Monitor
Dated: July 29, 1999
Received: July 30, 1999
Regulatory Class: II
21 CFR §884.2740/Procode: 85 HGM

Dear Mr. Clarke:

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): K983395

Device Name: Fetalgard 3000 Fetal Monitor

Indications For Use:

The Fetalgard 3000 Fetal Monitor is a Perinatal Monitoring System for showing graphically the relationship between maternal labor and the fetal heart rate by means of combining and coordinating display of uterine contraction and fetal heart rate measurements. This data is intended to aid in assessing the well-being of the fetus during pregnancy, labor, and delivery.

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K983395/S002

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)