K031320
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MAY 0 6 2003

Section 2 Summary of Safety and Effectiveness

Date: April 21, 2003

Submitter: GE Medical Systems *Information Technologies*
8200 West Tower Avenue
Milwaukee, WI 53223 USA

Contact Person: Karen M. Lunde
Sr. Regulatory Affairs Specialist
GE Medical Systems *Information Technologies*
Phone: 414-362-3329
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Device:

Trade Name: EK-Pro Arrhythmia Detection Algorithm

Common/Usual Name: Arrhythmia Detection Algorithm

Classification Names: 21 CFR 870.1025 Detector and Alarm, Arrhythmia

Predicate Device: K020290 Dash 3000/4000 Patient Monitor

Device Description: The EK-Pro Arrhythmia Detection Algorithm is a software algorithm that runs in GE Medical Systems *Information Technologies* patient monitors. When used in a patient monitor, the EK-Pro Algorithm processes the ECG data acquired by the patient monitor to detect various ECG arrhythmia events, and to compute and trend measurements that include heart rate, ventricular ectopic beats per minute, and ST segment deviations.

Intended Use: The EK-Pro Arrhythmia Detection Algorithm is intended for use under the direct supervision of a licensed healthcare practitioner. The intended use of the EK-Pro Algorithm is to monitor ECG parameter data on adult, pediatric and neonatal patients. The EK-Pro Algorithm is designed to monitor ECG parameter data in bedside, portable, and transport monitors that can operate in all professional medical facilities and medical transport modes.

Technology: The EK-Pro Arrhythmia Detection Algorithm employs the same functional technology as the predicate device in the monitoring of ECG parameter data.

Test Summary: The EK-Pro Arrhythmia Detection Algorithm and its host patient monitor complies with the voluntary standards as detailed in Section 9 of this submission. The following quality assurance measures were applied to the development of the EK-Pro Arrhythmia Detection Algorithm:

- Risk Analysis
- Requirements Specification Review
- Code Inspections
- Software Verification Testing
- Clinical Acceptance Testing (Validation)

Conclusion: The results of these measurements demonstrated that the EK-Pro Arrhythmia Detection Algorithm is as safe, as effective, and performs as well as the predicate device in monitoring ECG parameter data.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 6 2003

GE Medical Systems Information Tech
c/o Ms. Karen M. Lunde
Senior Regulatory Affairs Specialist
8200 West Tower Avenue
Milwaukee, WI 53223

Re: K031320
Trade Name: EK-Pro Arrhythmia Detection Algorithm
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm
Regulatory Class: Class III (three)
Product Code: MHX
Dated: April 21, 2003
Received: April 25, 2003

Dear Ms. Lunde:

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.

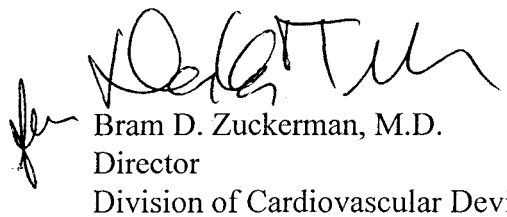
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Section 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 (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K031320

510(k) Number (if known): 510(k) filed on April 21, 2003

Device Name: EK-Pro Arrhythmia Detection Algorithm

Indications For Use:

The EK-Pro Arrhythmia Detection Algorithm is intended for use under the direct supervision of a licensed healthcare practitioner. The intended use of the EK-Pro Algorithm is to monitor ECG parameter data on adult, pediatric and neonatal patients. The EK-Pro Algorithm is designed to monitor ECG parameter data in bedside, portable, and transport monitors that can operate in all professional medical facilities and medical transport modes.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031320