K030104

JUN 11 2003

510(k) Summary

PRIME ECG ™ System with Diagnostic Algorithm

Common/Classification Name: Electrocardiograph as classified under 21 CFR 870.2340

Meridian Medical Technologies
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Contact: Jamil LaHam
General Manager, Cardiopulmonary Systems

Prepared: July 17, 2001

A. Legally Marketed Predicate Devices

The PRIME ECG System is substantially equivalent to the Hewlett Packard M1700A cleared under K911139. Both systems have the same intended use, which is to record electrocardiographical signals.

B. Device Description

The PRIME ECG System uses an 80-lead disposable electrode array referred to as a vest. The electrodes are screen-printed onto a clear plastic substrate. An 80 channel recording device is attached to the vest by means of two spring clips that interface with the printed lead lines. This means that 80 separate electrical signals are collected and stored.

The PRIME software also contains a diagnostic algorithm that may be used as an aid in diagnosing AMI. The algorithm provides an explanation of the measurements that were interpreted to reach the suggested diagnosis.

C. Indications for Use

The PRIME ECG is indicated for the recording of echocardiographic signals on the body surface.

D. Substantial Equivalence Summary

The PRIME ECG system with diagnostic algorithm is substantially equivalent to the PRIME system cleared under 510(k) K012414. It is also substantially equivalent to

marketed ECG systems, some of which also contain diagnostic algorithms.

In addition, a clinical study was performed that demonstrated that the PRIME ECG System diagnostic algorithm provides information that may assist in the diagnosis of acute myocardial infarction.

E. Technological Characteristics

The inclusion of a diagnostic algorithm does not change the technological characteristics of the PRIME ECG system.

F. Testing

The entire system has been tested to demonstrate compliance with IEC-601-1 (including its subparagraphs) Electro-Medical Equipment Safety Standard. The biocompatibility testing of the patient contact material showed that the material is safe for use. Performance testing to EC 11 standard demonstrates performance equivalent to marketed ECG systems. This testing demonstrates that the PRIME ECG System meets electrical and environmental safety standards for safe use.

G. Conclusions

Meridian Medical Technologies has demonstrated through its testing that the PRIME ECG with diagnostic algorithm is equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 2003

Meridian Medical Technologies
c/o Mr. Jamil LaHam
Vice President, Business Development
10240 Old Columbia Road
Columbia, MD 21046

Re: K030104
Trade Name: PRIME ECG Automated Analysis Software
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: April 10, 2003
Received: April 11, 2003

Dear Mr. LaHam:

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 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,

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

Enclosure

510(k) Number (if known): K030104

Device: PRIME ™ ECG System

Indications for Use:

The PRIME ECG System is intended for the recording of electrocardiographic signals from the body surface.

(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 K030104