V. 510(K) SUMMARY

510(k) SUMMARY

Heartscape Technologies Ltd's PRIME ECG® with enhanced Diagnostic Algorithm

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Date Prepared: 8th August 2008

Name of Device

PRIME ECG® with enhanced Diagnostic Algorithm

Common or Usual Name

PRIME ECG®

Classification Name/Product Code/CFR Reference

Electrocardiograph, classified under 21 CFR 870.2340

Predicate Devices

- PRIME ECG ™ System: manufactured by Meridian Medical Technologies Ltd (K012414)
- PRIME ECG ™ System with Diagnostic Algorithm: formerly manufactured by Meridian Medical Technologies Ltd, now manufactured by Heartscape Technologies Ltd. (K030104)

Intended Use / Indications for Use

The PRIME ECG® with enhanced Diagnostic Algorithm is intended to be used for the recording of electrocardiographic signals.

The PRIME ECG® with enhanced Diagnostic Algorithm is indicated for the recording of electrocardiographic signals on the body surface

Technological Characteristics

The device consists of the following components and accessories:

- **PRIME ECG Cart**

  Data recording and analysis is contained within a durable medical device that is used to record, analyze and display electrocardiographic signals from the body surface. The system features a power supply with battery back-up, signal acquisitioning and processing hardware and firmware, a computer and a software, including automated analysis software, a flat panel color display and a color printer.

  The PRIME ECG System incorporates computer processing that can present conventional ECG waveforms as color images displayed on a simulated torso. Each PRIME ECG recording captures body surface potentials for analysis. The PRIME ECG System translates the segments of the ECG waveform into ranges of color based on measured values. The range from yellow to red is assigned to positive values, with deep red assigned to the highest value. Green is assigned to neutral values and shades of blue are assigned to negative values with deep blue assigned to the highest negative value. This information allows physicians to identify areas of abnormality for interrogation.

- **PRIME ECG Algorithm**

  The PRIME Diagnostic Algorithm is an adjunct to the color displays of the underlying ECG waveforms to assist the physician in coming to a conclusion on the patient's cardiac status. The Diagnostic Algorithm uses multiple parameters of ECG potentials and ECG morphology to make a recommendation on whether the patient has a Normal, Abnormal or Acute MI condition. An explanation window describes to the physician the basis of the Diagnostic Algorithm conclusion. Thus, the physician is at liberty to interrogate the recommendation and agree to or override it.

- **PRIME ECG Single-Use Patient Vest**

  The PRIME ECG data recording and analysis system is attached to a single-patient electrode array (vest) that is placed on the patient in two parts consisting of a 64 lead

anterior and a 16 lead posterior segment. Electrodes and signal conduction pathways are screen-printed onto a clear plastic substrate. The vest is secured to the patient with a pre-applied conductive adhesive gel. The vest is a single use device and cannot be re-used.

The device complies with the relevant parts of EN60601 and AAMI 11. In overview:

- The device has features to isolate the patient from mains AC electricity supply, even in the event of fault conditions.
- The device is meant to be removed from contact with the patient before defibrillation. However, it has features to protect itself and users in the event of defibrillation of the patient whilst the device is still attached to the patient.
- The device conforms to the required standards for ElectroMagnetic Compatibility ("EMC"), both in its proof against external sources of interference and in limiting its own electromagnetic radiations.

Performance Data

The purpose of this 510(k) submission is to change the labeling of the device to incorporate the effects of enhancements to the Diagnostic Algorithm. These enhancements have resulted in an improved sensitivity in the detection of Myocardial Infarctions (MIs) over both the predecessor version (as cleared under K030104) and also the ubiquitous 12-lead ECG type of device.

The Company's IDE study (G990171) gathered data from a number of institutions to compare the sensitivity and specificity of both the 12-lead and PRIME ECG in the detection of MIs. This data was used as the basis for the 510(k) submission for K012414, demonstrating equivalence between the 12 lead as a predicate and PRIME ECG.

The IDE study had allowed the institutions to follow their normal protocol in the treatment of suspect MI. As a result there were a number of methods of confirmation of the diagnosis, no one methodology had been mandated. A sub-set of the IDE data was generated, the so called "FDA Troponin" set, where the MI diagnosis had been confirmed by Troponin as a Gold Standard. This sub-set was used to confirm that the Diagnostic Algorithm in the 510(k) submission for K030104 was at least as effective as the 12 lead in the detection of MI. Since the submission for K030104, the Company has added further enhancements to the Diagnostic Algorithm that improve its sensitivity to MI, whilst not significantly degrading its specificity. A table of comparison is below:

Table 1: Comparative Device Performance among patients with Biomarker confirmed MI

Test	True Positive (n=78)	False Positive (n=147)	Sensitivity	Specificity	Ratio of PRIME Sensitivity to 12-lead ECG
12-lead ECG	17	7	22%	95%	not applicable
PRIME ECG, physician interpretation (K012414)	26	10	33%	93%	1.5
PRIME Algorithm (K030104)	29	14	37%	90%	1.7
Enhanced PRIME Algorithm (this application)	37	17	47%	88%	2.1

The Company has created 3 training sets of cases (called Alpha, Beta and Charlie) for the development of the Diagnostic Algorithm. These cases have been drawn from Acute Coronary Syndrome patients attending a UK hospital and have no overlap with the FDA Troponin set. The Alpha, Beta and Charlie sets are used for the testing/training of possible enhancements to the Diagnostic Algorithm. The Troponin set is reserved solely for the final validation of MI detection performance.

Substantial Equivalence

The version of PRIME ECG, with enhanced Diagnostic Algorithm, that is the subject of this submission is as safe and effective as the predicate versions of PRIME ECG. The device has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the PRIME ECG with enhance Diagnostic Algorithm and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the PRIME ECG with enhanced Diagnostic Algorithm is as safe and effective as the predicate PRIME ECG with Diagnostic Algorithm and the PRIME ECG. Thus, the PRIME ECG with enhanced Diagnostic Algorithm is substantially equivalent.

Labeling Change

The main purpose of this 510(k) application is the desire to have a change to the labeling of the device that informs the user of the improved comparative performance of the device over the 12-lead EKG (the predicate of the original PRIME ECG) in the detection of ST Elevation Myocardial Infarction.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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SEP 1 2 2008

Heartscape Technologies Ltd
c/o Mr. Paul Phillips
Director
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BT19 7QY
United Kingdom

Re: K082312
Trade/Device Name: PRIME ECG ®
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: August 8, 2008
Received: August 13, 2008

Dear Mr. Phillips:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

IV. INDICATIONS FOR USE STATEMENT

Indications for Use Statement

510(k) Number (if known): K082312

Device Name: PRIME ECG®

Indications for Use:

The PRIME ECG® with enhanced Diagnostic Algorithm system is intended for the recording of electrocardiographic signals from the body surface

Prescription Use X AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K082312

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