K080421

EXHIBIT 2

Heart Sync LLC.
5643 Plymouth Rd.
Ann Arbor, Mi 48105
Phone: 800-828-4681
Fax: 734-213-5640
Contact: Stephen Shulman, Managing Partner

FEB 29 2008

January 16, 2008

510(k) Summary of Safety and Effectiveness

1. Identification of the Device:
   Proprietary-Trade Name: "Heart Sync" C-100 Adult Radiotransparent, Multifunction Electrodes and "Heart Sync" T-100 Adult Radiotranslucent Multifunction Electrodes

   Classification Name: Electrode, Electrocardiograph, Multi-Function; MLN
   Common/Usual Name: Defibrillator Electrode

2. Equivalent legally marketed devices: This is identical in function to the PadPro (K020203), and Katecho (K981737) and identical in design.

3. Indications for Use: The Heart Sync Adult Radio Transparent and/or Translucent Multi Function Electrodes are indicated for use in external pacing, defibrillation and monitoring applications as a non-sterile, disposable device for single patient use only. The electrodes provide the conductive interface between the defibrillator and/or the external transcutaneous (noninvasive) cardiac pacemaker and the patient's skin. The electrode is intended for use on adult patients. When a patient requires defibrillation, cardioversion or external pacing, these electrodes will be applied to the patient and connected to the instrument. This device is intended for use on defibrillators whose output is classified as low power (360 joule maximum).

4. Description of the Devices: Features & Benefits:

   The electrodes are multifunction because they can be used for defibrillation, pacing, cardioversion, and monitoring. Heart Sync electrodes can be used on Physio Control, Zoll, Hewlett-Packard, Philips and Welch-Allyn makes and models of monophasic and bi-phasic defibrillator. Radiotransparent and or Radiotranslucent "One Pad System" enables the pads to stay with the patient as they move through departments. Heart Sync has an electrode for any clinical need or patient situation. Heart Sync can provide onsite conversion of current cables to accept the Heart Sync electrodes. The polymer adhesive gel provides contact for uniform current distribution and more effective defibrillation and pacing. All Heart Sync products are Latex free.

Model differentiation:

Model	**Feature/difference**
C-100	Transparent to x-ray
T-100	Translucent to x-ray

5. Safety and Effectiveness, comparison to predicate device:

Comparison Areas	PadPro (K020203), and Katecho (K981737)	"Heart Sync" C-100 and T-100 Electrodes
Indications for use	For use as disposable electrodes for automatic and manual external defibrillators for monitoring, pacing, cardioversion, and defibrillation	SAME
Where used	Hospitals and Paramedic situations	SAME
Basic features	Radiotransparent and or Radiotranslucent, non sterile, latex free, single patient use, self adhesive, in sealed foil pouch.	SAME
Standard met	21CFR 898.12 Performance standard; ANSI/AAMI DF-80 2003 standard, self adhesive electrodes for monitoring and defibrillation	SAME

6. Conclusion In all respects, the Heart Sync System Defibrillator Electrodes are substantially equivalent to other electrodes that are legally marketed for this purpose. The device meets the standards referenced above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 29 2008

Heart Sync LLC
Mr. Mark Job
c/o Regulatory Technology Services
1394 25th Street, NW
Buffalo, MN 55313

Re: K080421
Trade/Device Name: Heart Sync C-100 and Heart Sync T-100
Regulation Number: 21 CFR 870.2360
Regulation Name: Electrocardiograph electrode
Regulatory Class: Class II (two)
Product Code: MLN
Dated: February 14, 2008
Received: February 15, 2008

Dear Mr. Job:

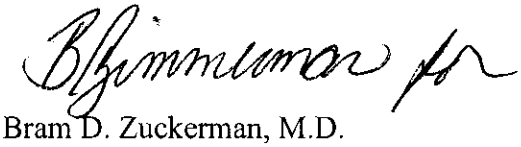
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 Biometric's (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

Indications for Use

510(k) Number (if known): _____

Device Name: "Heart Sync" C-100 Adult Radiotransparent Multifunction Electrodes and "Heart Sync" T-100 Adult Radiotranslucent Multifunction Electrodes

Indications for Use:

The Heart Sync Adult Radio Transparent Multi Function Electrodes and Heart Sync Adult Radiotranslucent Multifunction Electrodes are indicated for use in external pacing, defibrillation and monitoring applications as a non-sterile, disposable device for single patient use only. The electrodes provide the conductive interface between the defibrillator and/or the external transcutaneous (noninvasive) cardiac pacemaker and the patient's skin. The electrode is intended for use on adult patients. When a patient requires defibrillation, cardioversion or external pacing, these electrodes will be applied to the patient and connected to the instrument. This device is intended for use on defibrillators whose output is classified as low power (360 joule maximum).

Compatible with Medtronic Physio Control, Zoll, Hewlett-Packard, Philips Medical, and Welch-Allyn models of monophasic and bi-phasic defibrillators, external pacemakers.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K080421