K071391

SEP - 7 2007

PHILIPS

8. 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

1. The submitter of this pre-market notification is:

Philips Medical Systems
3000 Minuteman Road
Andover, MA 01810

Contact Person:
Mr. Paul Schrader
Senior Regulatory Affairs Mgr
Tel: 978-659-2404
Fax: 978-659-3610
Email: Paul.Schrader@philips.com

This summary was prepared on February 13, 2007.

2. The name of this device is the Philips HeartStart 12 Lead Transfer Station (catalog #989803142521). Classification names are as follows:

Classification	ProCode	Description
870.2300	74 MSX	System, Network and Communication, Physiological Monitors

3. The 12 Lead Transfer Station facilitates transmission of diagnostic 12 Lead ECG reports from Philips Defibrillators to ECG Management systems that recognize and accept digitized ECG records using the Philips published ECG schema. The Philips TraceMasterVue ECG System is a computer system which allows viewing, manual editing, printing, and archiving of digitized ECG records. TraceMasterVue communicates with Web-based clients, faxes, printers etc through an industry-standard client/server network with other hospital information systems.

4. The new device is substantially equivalent to the previously cleared M5100A TraceMasterVue ECG Management System cleared under K032103.

5. The product has a similar clinical intended use as the legally marketed predicate device. The only difference is that this SW is specific to 12 lead ECG records obtained from Philips defibrillator monitors.

6. The product has a subset of the technological characteristics as the legally marketed predicate devices.

7. Verification, validation, and testing activities establish the performance and functionality characteristics of the new device. Testing involved system level tests, integration tests and regression tests from hazard analysis. Pass/Fail criteria were based on the specifications and test results showed substantial equivalence. The results demonstrate that the functionality of the modified ECG Management System meets all performance claims.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 7 2007

Philips Medical Systems
c/o Paul Schrader
Senior Regulatory Affairs Manager
3000 Minuteman Rd.
Andover MA, 01810-1099

Re: K071391
Trade/Device Name: Philips Heartstart 12 lead transfer station, Model 9898031
Regulation Number: 21 CFR 870.2300
Regulation Name:
Regulatory Class: Class II
Product Code: MSX
Dated: August 9, 2007
Received: August 15, 2007

Dear Mr. Schrader:

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.

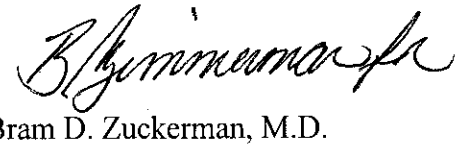
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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): K071391

Device Name: HeartStart 12 Lead Transfer Station

Indications For Use:

The HeartStart 12 Lead Transfer Station SW provides a diagnostic 12 lead ECG interface between Philips defibrillators and ECG management systems that can process XML formatted ECGs, such as the TraceMasterVue ECG Management system.

The HeartStart 12 Lead Transfer Station application also allows viewing, printing, archiving and further distribution of digitized ECG records.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K071391