K102974 p1/2

JAN - 4 2011

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 premarket notification is:

Gary Becker
Philips Medical Systems
Emergin
6400 N Congress Ave
Suite 1050, Boca Raton, FL 33487
Tel: 561 886-5124 Fax: 561 361-6991
e-mail: gary.becker@philips.com

This summary was prepared on September 30, 2010

2. The name of the device is the Philips Emergin Event Management. Classification names are as follows:

Device Panel	Classification	ProCode	Description
Cardiovascular Devices	§870.2300, II	MSX	Cardiac monitor (including cardiotachometer and rate alarm).

3. The Philips Emergin Event Management product is substantially equivalent to previously cleared Spacelabs device marketed pursuant to K062278, and Masimo Patient Safety Net K061932.

4. The introduction of a software only event management product.

5. The intended use is:

The Philips Emergin Event Management software provides healthcare professionals with supplemental information about patient alarms, technical alarms, nurse call alarms and system information messages (events). The product can route all or subsets of this information to selective remote devices such as pagers, phones, or marquees. Receipt of alarm messages or events by the external device, is not confirmed and delivery to the end device is not guaranteed. The primary alarm notification is the device producing the alarm or event. This product line is not intended to provide real-time information, nor is it a source of patient alarms, nor is it a replacement for alarming devices.

6. The product has the same technological characteristics as the legally marketed predicate devices.

7. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the device. Testing involved system level and regression tests as well as testing from the hazard analysis. The results demonstrate that the Philips meets all reliability requirements and performance claims.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Philips Medical Systems
c/o Mr. Gary Becker
Manager, Quality and Regulatory
Emergin
6400 N. Congress Ave Suite 1050
Boca Raton, FL 33487

JAN - 4. 2011

Re: K102974
Trade/Device Name: Philips Emergin Event Management System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II (two)
Product Code: MSX
Dated: September 30, 2010
Received: October 6, 2010

Dear Mr. Becker:

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.

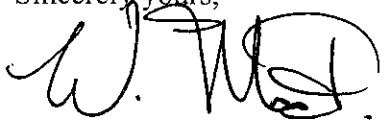
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for 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): K102974

JAN - 4 2011

Device Name: **Intellisphere Event Management**

Indications for Use:

The intended use of the Intellisphere Event Management product is to provide healthcare professionals with supplemental information about patient alarms, technical alarms, nurse call alarms and system information messages (events). The product can route all or subsets of this information to selective remote devices such as pagers, phones, or marquees. Receipt of alarm messages or events by the external device, is not confirmed and delivery to the end device is not guaranteed. The primary alarm notification is the device producing the alarm or event. This product line is not intended to provide real-time information, nor is it a source of patient alarms, nor is it a replacement for alarming devices.

Prescription Use XX
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
_____
(21 CFR 801 Subpart C)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K102974