K102757 P1/2

NOV - 5 2010

SECTION E: 510(K) SUMMARY

510(k) Summary

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

Submitter

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Registration Number: 3015876

Contact Person

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Date Summary Prepared

September 22, 2010

Device Name

LIFENET® System

Common Name

System, Network and Communication, Physiological Monitors

Device Classification

Classification name: Cardiac monitor (including cardiotachometer and rate alarm)
Device Class: II
Product Code: MSX
Classification Panel: Cardiovascular Device
Regulation Number: 21 CFR 870.2300

Identification of the Legally Marketed Device (Predicate Device)

LIFENET System (K093925)
Classification name: Cardiac monitor (including cardiotachometer and rate alarm)
Device class: II
Product Code: MSX
Classification Panel: Cardiovascular Device
Regulation Number: 21 CFR 870.2300

Description

The system is an optional data transmission system that is used in conjunction with monitoring devices. The system provides real time data transfer from the originating/transmitting device to a user selected remote receiving destination (RD). The users of the LIFENET System are qualified medical professionals and include Advanced Life Support providers (e.g. Paramedics) and Basic Life Support providers (e.g. Emergency Medical Technicians) in a variety of hospital and pre-hospital settings.

SECTION E: 510(K) SUMMARY (continued)

Description (continued)	The system is used in various areas of the hospital such as critical areas (emergency departments, critical care, operating room, etc.) and general duty floors (e.g. medical/surgical, clinics, physician offices, and cardiac catheterization labs). The system is also used for hospital transport (air and ground ambulance, in-hospital transport, etc). The modified system includes optional data management features that provide the user with expanded data management capabilities and increased efficiencies. Additionally, a new feature, the LIFENET Consult, provides users the capability to forward unaltered patient information for review and comment, by initiating a clinician consult. Upon receipt of patient data, health care professionals, using a hand held wireless device are able to view patient information and provide a "consult" reply to the hospital user intended for purposes of diagnosis, disposition, and therapy decisions.
Intended Use	The LIFENET System is an optional data transmission system that provides the capability to transmit real time 12-Lead ECG reports and other physiological data to a receiving destination at a remote location. Data is received from the field and can be used for diagnosis, disposition, and therapy decisions by qualified medical personnel.
Technological Characteristics of modified and predicate device	The modified LIFENET System performs and functions in the same manner as the predicate system. The modified LIFENET® System continues to use similar data transmission and connection technologies when compared to the previously cleared predicate. Optional data management capabilities have been expanded with the modified system and provide the user with increased system capability and efficiencies.
Conclusion of testing	The information in this 510(k) demonstrates that the modified LIFENET® System is substantially equivalent to the predicate LIFENET System with respect to safety, effectiveness, and performance.

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

Ms. Teresa Davidson
Physio-Control, Inc.
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P.O. Box 97006
Redmond, WA 98073-9706

NOV - 5 2010

Re: K102757
Trade/Device Name: LIFENET® 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: October 20, 2010
Received: October 22, 2010

Dear Ms. Davidson:

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,

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

Enclosure

K102757

SECTION D: STATEMENT OF INDICATIONS FOR USE

NOV - 5 2010

510(k) Number (if known): ~~Not yet assigned~~ → K102757

Device Name: LIFENET® System

The LIFENET System is an optional data transmission system that provides the capability to transmit real time 12-Lead ECG reports and other physiological data to a receiving destination at a remote location.

Data received from the field can be used for diagnosis, disposition, and therapy decisions by qualified medical personnel.

Prescription Use ___√___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Optional Format 3-10-98)

Donna R. Vo Nunes

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K102757