



Tools for medicine to help humankind

K964408

**510(K) SUMMARY
LIFESIGNS™ CARDIAC MONITORING SYSTEM
INSTROMEDIX, INC.**

510(k) Number K964408

Contact: Herbert J. Semler, M.D.

22 July, 1997

JUL 23 1997

The LifeSigns™ Cardiac Monitoring System collects vital signs data for diagnostic monitoring of stabilized patients, not at high risk for life-threatening arrhythmias, in an out-of-hospital environment. The monitored vital signs include ECG, SpO₂, heart rate, and blood pressure. The LifeSigns System is comprised of a monitor (LifeSigns™ Shuttle), a cradle (LifeSigns™ Commander), and central station software (LifeSigns™ Central Station). The Shuttle is a portable device, that acquires the patient ECG (one to 12 leads) using ECG electrodes, and the photometric SpO₂ data, and heart rate. The Commander provides the non-invasive oscillometric blood pressure measurement (as an option), and connects the Shuttle to a telephone line. The Central Station software operates on an IBM compatible personal computer, coupled by a DSVD (digital simultaneous voice and data) modem to a telephone line. The software provides support for data collection from the monitor and cradle, and supports display, editing, reporting and management of the collected vital signs data, patient demographics, and other associated data. The DSVD capability allows simultaneous voice and data communications between the patient and the central station personnel and between the cradle and the PC. The device is not intended to sound real time alarms. The LifeSigns System does not replace physician's care.

The LifeSigns System is substantially equivalent to aspects of the predicate systems, the Cardiac Alliance Buddy System, K864318 and K871748, the Healthtech Service Corporation Home Assisted Nursing Care System, K952979, and has features that are equivalent to features found in the predicate devices Mortara Eli 100 12-lead cardiograph, (ref: K920627), the CAS Medical Oscillomate Model 9300 (ref: K925402) and the Nonin Onyx Pulse Oximeter Model 9500, (ref: K942248). The LifeSigns System and its predicate both have the same general intended use of monitoring vital signs of patients in out-of-hospital settings. These systems use previously cleared elements to acquire the ECG, blood pressure, and SpO₂.

There are minor differences between the LifeSigns System and the predicates. For example, the Shuttle is physically much smaller and portable. With the Commander, three vital signs are measured. Simultaneous voice and data communications are possible between the patient site and the Central Station. And the Shuttle may be used separately by a healthcare professional to visualize the ECG, and obtain SpO₂ readings and heart rate, and with the Commander to obtain blood pressure. The predicate devices are significantly larger. These differences are not deemed to be significant in terms of the performance in acquiring diagnostic vital signs from the patient. Performance, safety, and efficacy of the LifeSigns System are substantially equivalent as compared to the predicate devices and components.

The LifeSigns System has been subjected to performance testing of vital signs measurements, performance to specifications, and electromagnetic environmental susceptibility and emissions. The results of the tests demonstrate that the LifeSigns System provides performance equivalent to the predicate devices and components, and meets applicable standards for performance and EMC compliance.

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Food and Drug Administration
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Rockville MD 20850

Herbert J. Semler, M.D.
Instromedix, Inc.
One Technology Center
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JUL 23 1997

Re: K964408
Poseidon Cardiac Monitoring System (PCMS)
Regulatory Class: II (two)
Product Code: 74 DPS
Dated: April 23, 1997
Received: April 24, 1997

Dear Dr. Semler:

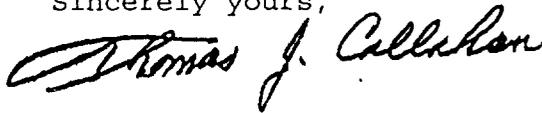
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K964408

Device Name: LifeSigns™ Cardiac Monitoring System

Indications For Use:

Monitoring of stable patients, not at high risk for life-threatening arrhythmias, after discharge from hospital stay, such as patients with compensated congestive heart failure, patients whose myocardial infarction is not recent, or patients with a stabilized heart condition following open heart surgery or coronary artery disease

Monitoring of patients in out-of-hospital convalescence settings

Monitoring of patients by physicians, clinics, or skilled care facilities

Any time a health care professional desires monitoring, measuring or recording of a patient's ECG, SpO₂, and/or blood pressure in an out of hospital residence setting

The device is not intended to sound real time alarms

This device does not replace physician's care

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. Page
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)