510(k) Summary

Fukuda Denshi model DS-5100E

Portable Patient Monitor

OCT - 3 1997

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR part 807.92.

The assigned 510(k) number is : K971131 .

Submitter:

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Date Prepared:

July 2, 1997

Device Name:

Proprietary Name:

model DS-5100E Portable Patient Monitor

Common Name:

Portable Patient Monitor

Classification Name:

Arrhythmia detector and alarm

Legally Marketed Device:

FUKUDA DENSHI model DS-5300 Patient Monitor, 510(k) number K964187. (The DS-5100E is a modification to the DS-5300, 510(k) number K964187.)

Description:

System

The DS-5100E Patient Monitor System is a pre-configured monitor meant to acquire and monitor physiological signals from patients. The system is designed to be used in an ICU, CCU, OR, ER, or Recovery areas of a hospital or clinic. Battery operation allows the DS-5100E to be used to monitor patients being transported within the healthcare facility. Patient ages from neonates to adults can all be monitored. Waveforms, numeric, and trend data from these patients are available to the clinician on the system's display or it may be printed on the system's recorder.

The Fukuda Denshi model DS-5100E Portable Patient Monitoring system consists of a main unit and a power unit.

The main unit of the system can be remotely located from the power unit and connected via a cable to provide continuous AC power. Batteries are installed into the main unit and the power unit to allow both parts to be disconnected from AC power and still function. The main unit may also be disconnected from the power unit and function independently on battery power.

Small, lightweight, but powerful in its application of technology, the DS-5100E system is portable and extremely easy to use.

High speed RISC (Reduced Instruction Set Computing) microprocessors, along with a high resolution color display and touch screen technology has made the DS-5100E a unique and intuitive patient monitor.

Upgrade capability has been made simple and quick through the use of high speed flash memory.

A Recorder module (HR-500), a multi-parameter telemetry transmitter (HLX-501), and an IC memory card are available as options.

Features

A 6 inch diagonal, active matrix TFT color display provides sharp, crisp waveforms and numerics.

A high quality, clear touch screen provides user interface that is simple and easy to use.

Up to 4 color waveforms can be displayed, measured and three can be recorded simultaneously on the optional HR-500 recorder.

Small and lightweight, the DS-5100E Main monitor unit is only 2.8 kg (6.2 lb.) with a battery, 5.1 kg(11 lb.) with the Power unit and 2 batteries.

Pre-configured monitoring parameters are ECG (3 leads), ST measurement, Arrhythmia, Respiration, 2 channels Invasive blood pressure, Non invasive blood pressure, Oxygen saturation, and 2 channels of Temperature.

Patient ages from neonates to adults can all be monitored by the DS-5100E.

High sample rates (1 second minimum) for graphic and tabular trend data provide highly accurate patient data.

Because there is no need for a cooling fan, operation is extremely quiet.

Use of low power, high speed flash memory allows for easy upgrades through a standard PCMCIA compatible IC card.

The AC power supply includes the battery charger for the built-in batteries, allowing the DS-5100E to be used during patient transport.

A recorder module (HR-500), a multi-parameter telemetry transmitter (HLX-501), and an IC memory card are available as options.

Statement of Intended Use:

The Fukuda Denshi model DS-5100E Patient Monitor provides a simple and reliable method to display and document the continuous hemodynamic, cardiovascular observations that are typically required of critically ill patients. These patients; neonate, pediatric, and adult; may be located in a hospital ICU, CCU, OR, ER, recovery, or other critical care unit. The DS-5100E can also be used to follow patients whose treatment requires close observation of specific physiological parameters. These patients may be in a clinic or other healthcare environment under the care of a physician. Battery operation allows the patients to continue to be monitored during transport. Parameters such as ECG, respiration, non-invasive or invasive blood pressures, temperature, and pulse oximetry may be monitored individually or in any grouping required by the clinician. This device is not intended for home use.

Comparison to Predicate Device

In summary, the DS-5100E system is pre-configured and smaller version of the DS-5300 patient monitor. Changes to the system include a reduction in size and weight, pre-configured parameters, battery operation, and simplification of the display. A single, identical central processing unit simplifies the design while allowing the majority of the DS-5300 software to be used without modification. The majority of the changes can be summarized as pre-configured, smaller, and battery powered.

Technological Characteristics

The DS-5100E utilizes a 6 inch TFT color LCD display with a high quality, analog touch screen. Physiological information is acquired through pre-configured inputs in a similar manner to the predicate device. A PCMCIA card interface provides a means to temporarily store data or to update the system's flash memory.

The pulse oximetry design is licensed from Nellcor Puritan Bennett and is the same as the Nellcor design used in the predicate device.

These technological differences do not affect the safety or efficacy of the device. Any safety issues that may be raised by a software controlled medical device are the same issues already addressed by the predicate device and are addressed in the systems hazard analysis and in the system validation.

Testing:

Laboratory testing was conducted to validate and verify that the Fukuda Denshi model DS-5100E Portable Patient Monitor met all design specifications and was substantially equivalent to the FUKUDA DENSHI model DS-5300. This testing consisted of all environmental testing identified in the FDA's DCRND November 1993 "Reviewer Guidance Document for Premarket notification Submissions" Draft Guidance Document. Additional testing was performed to demonstrate compliance with the ANSI/AAMI standards ES1-1993, "Safe current limits for electromedical apparatus"; EC11-1991, "Diagnostic electrocardiographic devices"; and EC13-1992, "Cardiac monitors, heart rate meters, and alarms." Finally, a hazard analysis of the system and its software was performed and testing was conducted to validate the systems overall operation.

Testing of the non-invasive blood pressure portion of the DS-5000 series' system was conducted according to the requirements outlined in the ANSI/AAMI standards SP10-1992, "Electronic or automated sphygmomanometers." The results of this testing has been reviewed as part of the DS-5300's 510(k), K964187. Data presented here demonstrates that the DS-5100E system performs at least as well as the model DS-5300.

Testing of the pulse oximetry portion of the DS-5000 series' system was conducted according to Nellcor Puritan Bennett's testing protocol. The results of this testing has been reviewed as part of the DS-5300's 510(k), K964187. Data presented here demonstrates that the DS-5100E system performs at least as well as the model DS-5300.

Testing of the arrhythmia and ST Level portions of the DS-5000 series' system were conducted according to AAMI Recommended Practice ECAR-1987, "Recommended Practice for Testing and Reporting Performance Results of Ventricular Arrhythmia Detection Algorithms. The results of this testing has been reviewed as part of the DS-5300's 510(k), K964187. The data is reproduced in tabular format in the appendix.

Although the device is neither life supporting nor life sustaining, diagnostic information derived from the use of the device and alarms generated by the device may be critical to the proper management of the patient.

So, the areas of risk for this device are the same as the predicate device and other devices in this class, and are the following:

- Electrical shock
  Excessive electrical chassis leakage current can disturb the normal electrophysiology of the heart, and possibly leading to the onset of cardiac arrhythmias.
- Misdiagnosis
  - Inadequate design of the signal processing and measurement circuitry or program can lead to generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.
  - Inadequate design of the device's software, used to make various measurements, can lead to generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

- Inadequate design of the systems ability to alert the users through audible and visual indicators, can lead to user mistrust and/or inadequate response to the patient's condition. If an inadequate response to the patient's condition should occur the patient may unnecessarily be placed at risk.

The design of the DS-5100E has taken into account all the above. The device is designed to meet UL 601, CSA 22.2 and AAMI standards for electrical safety for medical equipment to prevent the possibility of excessive electrical leakage current to the patient.

Conclusion:

The conclusions drawn from clinical and laboratory testing of the Fukuda Denshi model DS-5100E Portable Patient Monitor demonstrates that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate device, the Fukuda Denshi model DS-5300 Patient Monitoring System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

OCT - 3 1997

Mr. David J. Geraghty
Fukuda Denshi America Corp.
17725 NE 65th Street
Redmond, Washington 98052-4911

Re: K971131
DS-5100E Portable Patient Monitor
Regulatory Class: III (three)
Product Code: 74 DSI
Dated: July 7, 1997
Received: July 9, 1997

Dear Mr. Geraghty:

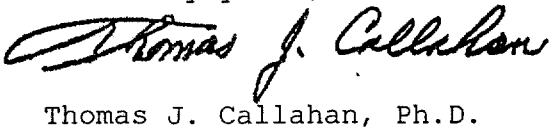
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (Premarket 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

Indications for Use Statement

510(k) Number (if known): K971131

Device Name: Fukuda Denshi model DS-5100E
Portable Patient Monitor

Indications For Use:

Use of the Fukuda Denshi model DS-5100E Portable Patient Monitor system is indicated in those clinical settings where

- Observations of one or more of the following parameters on an individual patient may be required: ECG (waveform, heart rate, ST-Level, and ventricular arrhythmias), respiration, non-invasive and/or invasive blood pressures, temperature, and/or pulse oximetry.
- The observations may include an audible and visual alarm if any of these parameters exceed values that are establish by the clinician.
- The observations may also include the individual or comparative trending of one or more of these parameters over a period of up to 24 hours.
- An instantaneous display of waveforms, numeric, and trended values is desired.
- a hard copy record of the physiological parameters, the alarmed conditions, or the trended values may be required.
- where the patient may need to be monitored while being transported within the healthcare facility.

Arth A Carlson

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

510(k) Number _____

PRESCRIPTION USE ✓