JUN 19 1998

Section 2

510(k) Summary
Fukuda Denshi Model DS-5000 Series
Telemetry Monitoring System

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: K980728

Submitter:

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Date Prepared:

February 20, 1998

Device Name:

Proprietary Name:

FUKUDA DENSHI DynaScope
model DS-5000 Series Telemetry System

Common Name:

Central Telemetry System

Classification Name:

Arrhythmia Detector and Alarm (§870.1025)

Legally Marketed Device:

Fukuda Denshi model DS-3300 ETR Telemetry System (K897063)
Fukuda Denshi model LX-3240 (K963057)
Nihon Kohden BSM-2100A (K914092)

Description:

The DS-5000 Series Telemetry Monitoring System consists of the Fukuda Denshi model DS-5800N central monitor (K970585), the LW-5500N central telemetry receiver, the HLX-501 multiparameter transmitter, and the LX-5120 ECG/Respiration transmitter. The units are microprocessor based software controlled devices. The LW-5500N can receive data for 4 or 8 patients and can be connected to the DS-5800N central monitor either directly, or via local area network (LAN). The LAN communication specifications for the DS-5800N remain unchanged. Each patient whose data is received by the LW-5500N is considered as a separate network node. Input signals are provided from the HLX-501 multiparameter transmitter connected to a bedside monitor, or from the LX-5120 ECG/Respiration transmitter that is attached to the patient.

Patient physiological data displays, controls, recordings and alarms are controlled from the DS-5800N central monitor. Recording can also be initiated from the bedside monitor, or from the patient worn transmitter. System functions, such as trending, arrhythmia and ST monitoring, and data access are available to the user from the central monitor. No changes were made to the arrhythmia or ST measurement algorithms.

The addition of multiparameter telemetry with the HLX-501 is a new telemetry feature, providing up to six waveforms and numeric data from the bedside monitor to the central station, and is the most significant change.

The new system uses PLL synthesized tuning instead of crystal replacement to select a new telemetry channel. The new system incorporates digital FSK data transmission in the UHF band.

Intended Use:

The DS-5000 Series Telemetry Monitoring System is intended to be used as a central station monitoring system for the evaluation of the cardiovascular system. It is intended to be used by or on the order of a physician or similarly qualified health care professional. The DS-5000 Series Telemetry Monitoring System is intended to be used in hospital environments; ER, ICU, a clinic, or similar settings. The DS-5000 Series Telemetry Monitoring System is intended to be used in those situations where the patient is being monitored by a Fukuda Denshi DS-5000 series bedside monitor, or patient worn telemetry transmitter where remote, central station monitoring is desired. This system is not intended for home use.

Technological Characteristics:

The DS-5000 Series Telemetry Monitoring System incorporates microprocessor controls in a similar manner to the predicate device(s). Data are transmitted from a bedside monitor, or a patient worn telemetry transmitter to the central receiver. The data are sent to the central monitor via direct HDLC communications or via Ethernet LAN communications protocol. These two methods of communication cannot be performed simultaneously.

The technological characteristics of the DS-5000 Series Telemetry Monitoring System do not effect 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 hazard analysis and system validation.

Testing:

Laboratory testing was conducted to validate and verify the DS-5000 Series Telemetry Monitoring System and its components to meet all design specifications and was substantially equivalent to the predicate device(s). 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. ANSI/AAMI ES1-1993, "Safe Current Limits for Electromedical Apparatus", and ANSI/AAMI EC13-1992, "Cardiac Monitors, Heart Rate Meters, and Alarms". Telemetry systems were tested for compliance with and have received FCC certification. Finally, a hazard analysis of the system components, and software was performed and testing was conducted to validate the systems overall operation.

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

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

- Electrical shock to the user.
  Excessive electrical chassis leakage current can disturb the normal electrophysiology of the heart, and possibly lead to the onset of cardiac arrhythmias.

- Misdiagnosis
  - Inadequate design of the transmission, and data acquisition for display can lead to 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 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.

The design of the DS-5000 Series Telemetry Monitoring System has taken into account all of the above. The device is designed to meet UL 2601-1, CSA 22.2, and AAMI standards for electrical safety for medical devices. The device has been tested to demonstrate compliance with these standards and to verify that the device specification have been met. Review of the test results does confirm that these objectives have been met.

Conclusion:

The conclusions drawn from the laboratory testing of the DS-5000 Series Telemetry Monitoring System demonstrate that the device is safe and effective, and performs as well as or better than the legally marketed predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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JUN 19 1998

Mr. David J. Geraghty
Regulatory Affairs Manager
Fukuda Denshi America Corporation
17725 NE 65th Street, Building C
Redmond, WA 98052

Re: K980728
Trade Name: Fukuda-Denshi DS-5000 Series Telemetry Monitoring System
Regulatory Class: III
Product Code: 74 DSI
Dated: February 20, 1998
Received: February 25, 1998

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 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). 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"(21CFR 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/dsma/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: K980728

Device Name: Fukuda-Denshi DS-5000 Series Telemetry Monitoring System

Indications For Use:

The Fukuda Denshi DS-5000 series Telemetry Monitoring system is indicated in those situations where centrally located hemodynamic monitoring (central station monitoring) of one or more patients's cardiovascular condition is desired and those patients are currently monitored by a Fukuda Denshi DS-5000 series bedside monitor, or is wearing a Fukuda Denshi telemetry transmitter. Use of this device is indicated only in a medically supervised healthcare environment (e.g., ER, ICU, or clinic). It is not intended for home use

(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, Respiratory,
and Neurological Devices
510(k) Number K980728

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)