JUN - 3 2004

Fukuda Denshi Model DS-5000
Telemetry Monitoring System
Special 510(k) Device Modification

Exhibit B
510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR part 870.92

The assigned 510(k) number is **(k) 033711**

Submitter: Fukuda Denshi U.S.A. Inc.
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Redmond, WA 98052
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Contact Person: Larry Walker
Regulatory Affairs Manager
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Tel: 425-881-7737
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Date Prepared: May 3, 2004

Device Name:

Proprietary Name: Fukuda Denshi DynaScope
Model DS-5000 Central Telemetry System

Common Name: Central Telemetry System

Classification: Arrhythmia Detector and Alarm (§870.1025)
Class III

Legally Marketed Device: Fukuda Denshi DS-5000 Telemetry Monitoring System **(K 980728)**
Minolta PULSOX-3Li Oximeter **(K010413)**

K033714

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Device Description:

The Fukuda Denshi model DS-5000 series Telemetry Monitoring System consists of a series of interface devices which include a central transmitter receiver, an HLX-501 Multi-parameter transmitter, LX-5120 patient worn ECG/Respiration transmitters, and a Fukuda Denshi DS-5000 series Central Patient Monitor (**K970585, K000746, K020084**). The unit's are processor based software control devices. The receiver module can receive data for 4 or 8 patients and can be connected either directly or by local area network (LAN) to the DS-5000 series Central Patient Monitor. Each patient data when received at the central transmitter receiver is considered as a separate network node. Input signals are provided from the patient worn LX series transmitters or from the HLX-501 Multi-parameter transmitter when connected to a Fukuda Denshi DS-5000 series patient monitor.

Patient physiological data displays, controls, recordings and alarms are controlled from the Central Patient Monitor. Recordings can also be initiated from the bedside monitor or from the patient worn transmitters. System functions such as trending, arrhythmia and ST monitoring and data access are available to the user from the central monitor.

The HLX-501 multi-parameter transmitter may provide up to six waveforms and numeric data from the bedside monitor. Parameter monitored may include ECG, SpO2, Resp, BP, NIBP and Temp.

The patient worn LX-5120 transmitter provides monitoring of ECG and Respiration parameters.

The modified transmitter subject to this submission, the patient worn LX-5630 provides ECG and Respiration monitoring identically as the LX-5120 and adds SpO2 transmission through the integration of an Pulse Oximetry OEM module designed and manufactured by Konica Minolta Sensing Inc and cleared as the Minolta Pulseox-3 LI **(K010413).**

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Statement of Intended Use:

The DS-5000 Series Telemetry Monitoring System is intended to be uses 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 - 7000 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 addition of the model LX-5630 patient worn transmitter, to the DS-5000 series Telemetry Monitoring System does not change the fundamental technology of the unmodified system. Data is transmitted from a telemetry transmitter to a Fukuda Denshi Central Patient Monitor utilizing the same central transmitter receiver. The modification allows the addition of SpO2 monitoring from a patient worn transmitter. The monitoring of SpO2 has been available as part of the DS-5000 series Telemetry Monitoring System, through the use of the multi-parameter transmitter (model HLX-501) when connected to a DS-5000 series bedside monitor. The LX-5630 adds SpO2 monitoring, through the integration of the OEM supplied SpO2 module designed and manufactured by Konica Minolta Sensing Inc as cleared as the Minolta PULSOX - 3Li Pulse Oximetery module **(K010413)**, to the ECG and Respiration monitoring capabilities found in the model LX-5120 patient worn transmitter which was cleared in the original submission.

The technology characteristics of the modified transmitter, Model LX-5360, do not affect the safety or efficacy of the DS-5000 series Telemetry Monitoring System. Any safety issues that may be raised by a software control medical device are either the same issues already addressed during the submission of the unmodified devices or are addressed in the hazard analysis and verification/validation process.

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Testing:

Verification and validation testing were conducted to establish the performance and reliability characteristics of the modified device. Testing involved safety testing from the risk analysis including electrical safety testing, EMC testing and radio telemetry testing. Additionally pulse oximetry laboratory accuracy testing was conducted to verify compliance to clinical testing results submitted with the OEM produced predicate oximetry device. Acceptance criteria were based on the specifications cleared for the predicate devices and test results showed substantial equivalence

Conclusion:

The conclusion drawn from the verification and validation testing of the modified DS-5000 Series Telemetry Monitoring System demonstrates that the device is safe and effective and performs as well or better than the legally marketed predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 3 2004

Fukuda Denshi USA, Inc.
c/o Mr. Larry D. Walker
Regulatory Affairs Manager
17725 N.E. 65th St., Building C
Redmond, WA 98052

Re: K033711
Trade Name: Fukuda Denshi DS-5000 Telemetry Monitoring System and LX-5630 Transmitter
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm
Regulatory Class: II (two)
Product Code: MHX
Dated: May 3, 2004
Received: May 5, 2004

Dear Mr. Walker:

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 such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

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

Enclosure

Fukuda Denshi Model DS-5000
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Exhibit E
Indication for Use

510(k) Number if Known	K033711
Device Name	Fukuda Denshi DS-5000 Telemetry Monitoring System
Indication for Use	The Fukuda Denshi DS-5000 series Telemetry Monitoring System is indicated in those situations where centrally located homodynamic monitoring (central station monitoring) of one or more patients cardiovascular condition is desired and those patients are currently monitored by a Fukuda Denshi 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. This device is intended for Prescription Use Only

Prescription Use X (Part 21 CFR 801 Subpart D) And/Or Over-The Counter Use ____ (21 CFR 807 Subpart C)

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

Concurrence of CDHR, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033711

Page 1 of