REVISED 510(k) Summary 1-30-2011

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Fukuda Denshi Model LX-7230KM/7230N Transmitter

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: **K103134**.

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- Date Prepared: October 8, 2010

Device Name:

- Proprietary Name : Fukuda Denshi Model LX-7230KM/7230N Transmitter
- Common Name: Telemetry Transmitter
- Product Code: MHX
- Regulation Number: 21 CFR Part 870.1025
- Class: II
- Review Panel: Cardiovascular

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Legally Marketed Device:

Fukuda Denshi model LX-5630 Transmitter, #**K033711**

In addition, the SpO_2 measurement function of the LX-7230KM/7230N Transmitter utilizes technology incorporated into previously cleared devices and several OEM manufactured modules that have received separate clearance from the FDA as follows:

The SpO_2 measurement technology used in the LX-7230KM is the same as that used in the Konica Minolta model "Pulsox-300/300i" cleared under 510(k) # **K053419**. We have made no modifications to Konica Minolta SpO2 module or sensors under K053419.

The SpO_2 measurement technology used in the LX-7230N is the same as that used in the Nellcor Puritan Bennett model "OxiMax N-600x Pulse Oximeter" cleared under 510(k) # **K060576**. We have made no modifications to the Nellcor SpO2 module or sensors under K060576.

Description:

The Fukuda Denshi model LX-7230KM/7230N is a patient worn Transmitter that transmits physiological data such as ECG, respirogram, arterial oxygen saturation (SpO_2), plethysmograph, and pulse rate from a patient to a Fukuda Denshi Central Monitor. The front LCD display information such as ECG, heart rate, respirogram, respiration rate, SpO_2, plethysmograph, pulse rate, pulse amplitude level, battery level, and the conditions of the ECG electrodes and SpO_2 sensor. For the SpO_2 measurement, the LX-7230N utilizes Nellcor SpO2 module technology (K060576) and the LX-7230KM utilizes Konica-Minolta SpO2 module technology (K053419). Both transmitters can only be used as an interface device of the previously cleared Fukuda Denshi Central Monitor (**K970585, K000746, K020084**) utilizing the central telemetry receiver (**K980728**). Both transmitters utilize digital FSK (frequency shift keying) technology and operate in the WMTS 608 to 614 MHz transmission frequencies. One or two channel ECG waveforms are selectable with lead selection available using the two buttons (Enter and ▽) on the front panel. (In case of using a 3-electrode lead cable or a 5-electrode chest lead cable). Both transmitters are battery powered using 2 AA alkaline batteries with available continuous operation for 6 days (LX-7230KM) or 3 days (LX-7230N). The LX-7230KM/7230N is small and lightweight at 190 grams including batteries. The physical dimensions of the device are 72 mm (W) x 98 mm (H) x 24.8(D) mm.

Additional details regarding the device description can be found in the device's Operation Manual (**Exhibit # 3**) and **Section 10**, "Device Information (Modified Device) for Fukuda Denshi model LX-7230KM/7230N Transmitter". Also included in **Section 10** are the subject device's Engineering Drawings, such as external appearance.

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The modifications to the Fukuda Denshi model LX-5630 Transmitter include the replacement of a later version of Konica Minolta SpO_2 module, adding an optional SpO_2 module from Nellcor, changes to the overall dimensions of the device, and changes to the ECG lead wire set.

The new modified device, LX-7230KM, utilizes the same fundamental technology of ECG and Respiration measurement as the current patient worn transmitter LX-5630 (**K033711**) and, for SpO_2 measurement, utilizes the latest version SpO_2 module built and manufactured by Konica-Minolta and cleared as the PULSOX-300/300i Oximeter (**K053419**). We have made no modifications to Konica Minolta SpO2 module or sensors under K053419.

The new modified device, LX-7230N, utilizes the same fundamental technology of ECG and Respiration measurement as the current transmitter LX-5630 (**K033711**) and, for SpO_2 measurement, utilizes the SpO_2 module built and manufactured by Nellcor and cleared as the N-600x Pulse Oximeter (**K060576**). We have made no modifications to Nellcor SpO2 module or sensors under K060576

The LX-7230KM/7230N Transmitter weighs 190 grams including batteries and has dimensions of 72(W) x 98(H) x 24.8(D) mm. The modified device is also powered by two (2) AA size batteries as before.

The LX-7230KM/7230N Transmitter is a WMTS compliant device and operates only preprogrammed channels in the 608 to 614 MHz bandwidth as before.

Statement of Intended Use:

The DS-7000 Series Telemetry Monitoring System is intended to be used as 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 healthcare professional. The DS-7000 Series Telemetry Monitoring System is intended to be used in hospital environments: ER, ICU, a clinic or similar settings. The DS-7000 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.
The intended use of the modified device as described in the labeling has not changed as a result of the modifications.

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Technological Characteristics:

The Fukuda Denshi model LX-7230KM/7230N Transmitter incorporates the identical technology as the predicate devices. The device provides a means with interfacing with a patient, transmitting specific physiological data to a Fukuda Denshi Central Monitor (**K970585, K000746, K020084**) utilizing the central telemetry receiver (**K980728**), and processing the data for display of numeric values and waveforms on the front LCD.

The technology characteristics of the LX-7230KM/7230N Transmitter do not affect the safety or efficacy of the device. Any safety issues raised by a software control medical device are either the same issues already addressed by the predicate devices or are addressed the system hazard analysis, or in the system validation.

Testing:

The Fukuda Denshi model LX-7230KM/7230N Transmitter has been subjected to extensive safety, environmental and performance testing. Final testing for the device included various performance tests for the device designed to insure that all functional and performance specifications were met. We have made no modifications to Konica Minolta SpO2 module or sensors under K053419 or to Nellcor SpO2 module or sensors under K060576. Additionally the device was host tested at the previously noted OEM engineering test facility to insure that performance and functional specifications for their supplied module were met.

Conclusion:

In conclusion, drawing from laboratory testing, validation and risk Analysis, the Fukuda Denshi model LX-7230KM/7230N Transmitter demonstrates that this device is as safe and effective as and performs as well as the legally marketed predicate device, the Fukuda Denshi model LX-5630 Transmitter 510(k) #**K033711**.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

Fukuda Denshi USA, Inc.
c/o Doug Blakely
Regulatory Director
17725 NE 65th Street, Bldg. C
Redmond, WA 98052

MAR 11 2011

Re: K103134
Trade/Device Name: Fukuda Denshi Model LX-7230KM/7230N Transmitter
Regulation Number: 21 CFR 870.1025
Regulation Name: Telemetry Transmitters
Regulatory Class: Class II (two)
Product Code: MHX
Dated: February 25, 2011
Received: March 3, 2011

Dear Mr. Blakely,

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,

Donna R. Zuckerman

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

Enclosure

Indications for Use

510(k) Number (if known): **K103134**

Device Name: **Fukuda Denshi Model LX-7230KM/7230N Transmitter**

Indications For Use:

The DS-7000 Series Telemetry Monitoring System is intended to be used as 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 healthcare professional. The DS-7000 Series Telemetry Monitoring System is intended to be used in hospital environments: ER, ICU, a clinic or similar settings. The DS-7000 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.

Prescription Use __X__ AND/OR
Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. McNeil
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K103134