April 16, 2018

Fukuda Denshi USA, Inc.
Doug Blakely
Director, Regulatory Affairs
17725 NE 65th Street, Building C
Redmond, Washington 98052

Re: K173226
Trade/Device Name: Fukuda Denshi CardiMax FX-8322 Electrocardiograph
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: September 28, 2017
Received: October 3, 2017

Dear Doug 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173226

Device Name
Fukuda Denshi CardiMax Model FX-8322 Electrocardiograph

Indications for Use *(Describe)*

The Fukuda Denshi CardiMax Model FX-8322 Electrocardiograph is intended to acquire, analyze, display, and record resting electrocardiographic information from adult and pediatric populations. The basic system delivers three (3), six (6) or twelve (12) channels of ECG parameters (waveform, arrhythmia and rhythm measurements, interpretation and heart rate). The device is indicated in situations where an instantaneous display of ECG information or a hard copy record may be required. The device is intended to be used under the direct supervision or a licensed healthcare practitioner, by trained operators in a hospital or medical professional's facility.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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: **K173226**

Submitter: Fukuda Denshi USA, Inc.
17725 NE 65th St. Building C
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Tel: 425-881-7737
Fax: 425-869-2018

- Contact Person: Doug Blakely
  Director- Regulatory Affairs
  Fukuda Denshi USA, Inc.
  17725 NE 65th Street, Building C
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- Date Prepared: September 28, 2017

Device Name**:**

- **Trade Name:** Fukuda Denshi CardiMax Model FX-8322 Electrocardiograph
- **Regulation Name:** Electrocardiograph
- **Product Code:** **DPS** – Electrocardiograph
- **Regulation Number:** 21 CFR Part 870.2340
- **Device Class:** II
- **Review Panel:** Cardiovascular

Predicate Devices:

Fukuda Denshi Cardiograph Model FX-4010 Electrocardiograph, 510(k) # **K981066**.

The 12-Lead ECG analysis software module which modified any functions used in the FX-8322 is the same as that used in the Fukuda Denshi CardiMax model FX-4010 Multi Channel Electrocardiograph cleared under 510(k) # **K981066** and the Nihon Kohden Cardiofax model ECG-1350A cleared under 510(k) **#K072217**.

Device Description:

The Fukuda Denshi CardiMax Model FX-8322 Electrocardiograph is meant to acquire and record cardiac action potentials from patients. The device is design to be used in Recovery areas of the hospital or clinic. Patient ages from neonates to adults can all be applied. Waveforms, heart rate and analysis data from these patients are available to the diagnostic or may be recorded.

The FX-8322 is an Electrocardiograph. The main part consists of the Main Control Board (model: PCB-7285), the Operation Board (model: PCB-7234), the AMP Board (model: PCB-6731), the LCD Module (model: TX17DO1VM2CAA / FD-42-3D), the Power Supply Unit (model: APAU003-07), the Recorder Unit. In addition, the Patient Cable (model: CP-105L), the Chest Electrode (model: TEE-01 / TEE-01RA) and the Limb Electrode (model: TEE-43 / TEE-43RG). Furthermore, the device is designed so it can be connected to USB, LAN cable, Serial cable, SD Card and an external monitor. There are two (2) types of the external monitors depending on the display size desired:

L-560T-C: 17 inch LC monitor
MX-191: 19 inch LC monitor

The user interfaces, touch screen panel and key panel are located on the top surface of the device. The touch screen display has a variable number of keys that are activated by software and depends on the display/function that the user selects. In addition, there are sixty-five (65) fixed keys on the bottom of the LCD display.

The Fukuda Denshi Model CardiMax FX-8222 provides acquiring and recording ECG (standard 12 lead), heart rate along with the standard 12-Lead ECG analysis software module.

The Fukuda Denshi Model CP-105L Patient Cable provides the ECG signal through Electrocardiograph Electrodes.

Additional standard features include the LAN connection, which is a proprietary network system through either a built in Ethernet LAN connector for connection to the hospital system. Standard features include a USB connection and SD Card connection, which is intended to store the ECG data and connect the USB Wireless LAN adaptor, and the Serial Connection, which is intended to connect to an External Monitor connection and the R-sync connection available when an R-Wave synchronized signal is needed.

Statement of Intended Use:

The Fukuda Denshi CardiMax Model FX-8322 Electrocardiograph is intended to acquire, analyze, display, and record resting electrocardiographic information

from adult and pediatric populations. The basic system delivers three (3), six (6) or twelve (12) channels of ECG parameters (waveform, arrhythmia and rhythm measurements, interpretation and heart rate). The device is indicated in situations where an instantaneous display of ECG information or a hard copy record may be required. The device is intended to be used under the direct supervision of a licensed healthcare practitioner or by trained operators in a hospital or medical professional's facility.

Technological Characteristics:

The FX-8322 incorporates the identical technology as the predicate devices. The device provides a means with interfacing with a patient, collecting and processing parameter specific physiological data that can be displayed, recorded or stored.

The technology characteristics of the FX-8322 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 in the system hazard analysis, or in the system validation.

Testing:

The Fukuda Denshi CardiMax Model FX-8322 Electrocardiograph 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.

The FX-8322 has also been tested to assure compliance to the requirements of various published standards including the following:

General safety standards

- IEC 60601-1: 2005+A1: 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance. 3rd Edition
- IEC 62304: 2006 Medical device software – Software life cycle processes
- IEC 62366: 2007 Medical devices -- Application of usability engineering to medical devices
- ISO 14971: 2007 Medical devices -- Application of risk management to medical devices

Individual standards

- ANSI/AAMI EC53: 2013 ECG trunk cables and patient leadwires

- IEC 60601-2-25: 2011 Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs

- ISO 15233-1: 2008 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements

EMC standards

- IEC 60601-1-2 Ed.3.0: 2007 Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

Conclusion:

In conclusion, drawing from laboratory testing, validation, and risk analysis, the Fukuda Denshi CardiMax Model FX-8322 Electrocardiograph demonstrates that this device substantially equivalent and performs as well as the legally marketed predicate devices, the Fukuda Denshi CardiMax model FX-4010Multi Channel Electrocardiograph cleared under 510(k) # K981066 (12-Lead ECG analysis portion) and the Nihon Kohden Cardiofax model ECG-1350A cleared under 510(k) # K072217.