K981066

AUG 3 1 1998

Section 2

510(k) Summary

Fukuda Denshi model FX-4010

Multi Channel Electrocardiograph

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: K981066 .

Submitter:

FUKUDA DENSHI AMERICA CORP.
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Contact Person:

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Date Prepared:

March 10, 1998

Device Name:

Proprietary Name:

Fukuda Denshi: CardioMax, model FX-4010
Multi Channel Electrocardiograph

Common Name:

Multi Channel Interpretive Electrocardiograph

Classification Name:

Electrocardiograph

Legally Marketed Device:

FCP-2155, Multi Channel Interpretative ECG (K971440)

Description:

The Fukuda Denshi model FX-4010 Multi Channel Electrocardiograph is a portable, multi channel, interpretive, automatic or manual electrocardiograph. This electrocardiograph is designed to produce a thermally printed recording of the electrical signals produced by the heart. The size of the unit is 37.8(W) x 33.8(D) x 10.1(H) cm and weighs approximately 8 kg.

Intended Use:

This Fukuda Denshi model FX-4010 Multi Channel Electrocardiograph is intended to be used for the evaluation of the cardiovascular system. The FX-4010 will acquire and record ECG waveforms. Also, the FX-4010 can provide ECG interpretation. The FX-4010 is to be used by or on the order of a physician or similarly qualified health care professional. The FX-4010 may be used in all hospital environments; ER, OR, ICU, etc.; doctors' offices; clinics; or similar settings. This device is intended to be used on any patient; neonate, pediatric, or adult; where the placement of EKG electrodes does not interfere with or complicate the treatment of the patient.

The interpretive feature is to be used on any patient, at least one (1) year old, where the placement of EKG electrodes does not interfere with of complicate the treatment of the patient. This device is not intended for home use.

Technological Characteristics

The Fukuda Denshi model FX-4010 Multi Channel Electrocardiograph incorporates the microprocessor, thermal printer, input and output channels, measurement and interpretive analysis, and LCD technology similar to the predicate device. The FX-4010 has a port for plugging in a 2-megabyte memory card for storing data. Also, the 4010 has the ability to have accessory cartridges and modules to enables its basic ECG functions. A rechargeable battery is available on both devices.

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 addressed in the system's hazard analysis and the system validation.

Testing:

Laboratory testing was conducted to validate and verify the Fukuda Denshi model FX-4010 Multi Channel Electrocardiograph met all design specifications and was substantially equivalent to the FUKUDA DENSHI model FCP-2155. 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 ANSI/AAMI ES1-1993, "Safe current limits for electromedical apparatus," ANSI/AAMI EC11-1991, "Diagnostic Electrocardiographic Devices". Finally, a hazard analysis of the system and its 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 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.

The design of the FX-4010 has taken into account all the above. The device is designed to meet UL 2601, 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 Fukuda Denshi model FX-4010 Multi Channel Electrocardiograph 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 FCP-2155 Multi Channel Electrocardiograph (K971440).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 1998

Mr. Richard Queen
Fukuda Denshi America Corporation
17725 NE 65th Street
Redmond, WA 98052

Re: K981066
Fukuda Denshi CardioMax Model FX-4010,
Multi Channel Electrocardiograph
Regulatory Class: III (three)
Product Code: 74 LOS
Dated: July 8, 1998
Received: July 15, 1998

Dear Mr. Queen:

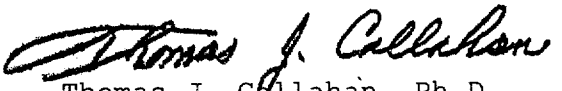
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28,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

Indications for Use Statement

510(k) Number (if known): K981066

Device Name: Fukuda Denshi: CardioMax, model FX-4010, Multi Channel Electrocardiograph

Indications For Use:

Use of this device is indicated where a physician or healthcare professional requires information about the electrical events within the myocardium using waveforms recorded from the body's surface during depolarization and repolarization of the atrium and ventricles. The FX-4010 is indicated where a clinician seeks advisory interpretive measurement, and diagnostic statements that would require confirmation by a physician. Also, can provide measurement data, R to R timing measurements with trend infotmation and interpretation of arrhythmia to the clinician.

The basic EKG and recording features of this device are intended to be used on any patient; neonate, pediatric, or adult; where the placement of EKG electrodes does not interfere with or complicate the treatment of the patient. The interpretive feature of this device is intended to be used on any patient, at least one (1) year old, where the placement of EKG electrodes does not interfere with or complicate the treatment of the patient. This device 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)

Mark Kramer

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K981066

Prescription Use ✓ or Over-The-Counter Use ____
(Per 21 CRF 801.109)