

K970585

Section 2
510(k) Summary
Fukuda Denshi Model DS-5800N
Central Station Monitor

SEP - 9 1997

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 : K970585

Submitter:

FUKUDA DENSHI AMERICA CORP.
17725 NE 65th St., Building C
Redmond WA 98052-4911
Tel: 425/881-7737
Fax: 425/869-2018

Contact Person:

David J. Geraghty
Regulatory Affairs Manager
FUKUDA DENSHI - Seattle Branch
17725 NE 65th St., Building C
Redmond WA 98052-4911
Tel: 425/881-7737
Fax: 425/869-2018

Date Prepared:

May 15, 1997

Device Name:

Proprietary Name:

FUKUDA DENSHI DynaScope
model DS-5800N
Central Station Monitor

Common Name:

Central Station Monitor

Classification Name:

Arrhythmia Detector and Alarm

Legally Marketed Device:

FUKUDA DENSHI model DS-3300 Patient Monitor;
510(k) number K894628

Description:

The DS-5800N is a microprocessor based software controlled device. This central station monitor incorporates a 15 inch color CRT display. Up to eight patients can be centrally monitored simultaneously from the ICU, CCU, or other areas of the hospital. Input signals are provided by Fukuda Denshi 5000 series patient monitoring equipment that have been submitted under separate 510(k) filings.

The DS-5800N is a true central station. All data is provided by external sources, Fukuda Denshi 5000 series patient monitoring equipment, for presentation and printout at central. The DS-5800N will act as a remote keypad for the bedside monitors, utilizing its built in touch screen or optional keyboard. The central station will act as the LAN administrator for monitors connected to the Fukuda Denshi patient monitoring LAN and display data from any eight of up to 48 bedside monitors.

The DS-5800N will present alarm information, ECG analysis, and other hemodynamic data acquired and processed by bedside monitors. The DS-5800N does not perform any of these functions. The DS-5800N is used to announce and control arrhythmia alarm information from the bedside.

Intended Use:

This device is intended to be used as a central station monitor 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-5800N is intended to be used in hospital environments; ER, ICU, a clinic; or similar settings. This device is intended to be used in those situations where the patient is being monitored by a Fukuda Denshi DS-5000 series bedside patient monitor and remote, central station monitoring is desired. This device is not intended for home use.

Technological Characteristics

The DS-5800N incorporates a microprocessor in a similar manner to the predicate device. Data is acquired from "intelligent" bedside monitors via an Ethernet, twisted pair LAN and presented for display and/or printout. LAN communication is managed by the central station. A touch screen, placed over the CRT offers the operator a means of entering information into the system and controlling the central station.

The technological characteristics of the DS-5800N 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 systems hazard analysis and in the system validation.

Testing:

Laboratory testing was conducted to validate and verify the FUKUDA DENSHI DynaScope model DS-5800N Central Station Monitor met all design specifications and was substantially equivalent to the FUKUDA DENSHI model DS-3300's central station function. 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. Finally, a hazard analysis of the system and its software was performed and testing in a simulated environment was conducted to validate the overall system.

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 other devices in this class, and are as follows:

- Electrical shock, to the patient or user.
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 data acquisition and display and printer output 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 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-5800N has taken into account all the above. The device is designed to meet UL 601, CSA 22.2 and AAMI standards for electrical safety for medical equipment. The device has been tested demonstrate compliance with these standards and to verify that the device does meet all specifications. Review of the test results does confirm that these objectives have been successfully achieved.

Conclusion:

The conclusions drawn from the laboratory testing of the FUKUDA DENSHI DynaScope model DS-5800N Central Station Monitor demonstrate 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 DS-3300, K894628.

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

- Electrical shock, to the patient or user.
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 data acquisition and display and printer output 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 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-5800N has taken into account all the above. The device is designed to meet UL 601, CSA 22.2 and AAMI standards for electrical safety for medical equipment. The device has been tested demonstrate compliance with these standards and to verify that the device does meet all specifications. Review of the test results does confirm that these objectives have been successfully achieved.

Conclusion:

The conclusions drawn from the laboratory testing of the FUKUDA DENSHI DynaScope model DS-5800N Central Station Monitor demonstrate 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 DS-3300, K894628.

COMPLIANCE CERTIFICATE

I certify that in my capacity as Regulatory Affairs Manager and official FDA correspondent for FUKUDA DENSHI AMERICA CORP. that I have conducted a reasonable search of all information known or otherwise available about the types and causes of safety or effectiveness problems that have been reported for Arrhythmia Detectors and Alarms. I further certify that I am aware of the types of problems to which Arrhythmia Detectors and Alarms are susceptible and that to the best of my knowledge, the attached summary of the types of causes of safety or effectiveness problems about Arrhythmia Detectors and Alarms is complete and accurate.

I hereby certify that the attached software development process and quality assurance procedures were adhered to and that all testing performed demonstrates that the functional requirements were met and that the system specifications were fulfilled.



Signature

David J. Geraghty

Name

Regulatory Affairs Manager
Fukuda Denshi - Seattle Branch
Official Correspondent for Fukuda Denshi America Corp.

Title



SEP - 9 1997

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Mr. David J. Geraghty
Fukuda Denshi America Corporation
17725 NE 65th Street
Redmond, Washington 98052

Re: K970585
Model DS-5800N Central Station Monitor
Regulatory Class: III (three)
Product Code: 74 DSI
Dated: June 9, 1997
Received: June 11, 1997

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 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 (Pre-market 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.

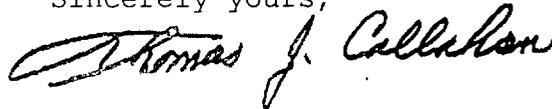
Page 2 - Mr. David J. Geraghty

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/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): K970585

Device Name: Fukuda Denshi model DS-5800N
Central Station Monitor

Indications For Use: Use of the DS-5800N is indicated in those situations where centrally located secondary hemodynamic monitoring is desired of patients that are currently primarily monitored at bedside by a Fukuda Denshi DS-5000 series bedside monitor. The DS-5800N is indicated where information from the DS-5000 series bedside monitor would include any or all of the following parameters: ECG, respiration, invasive and/or non-invasive blood pressures, temperature, pulse oximetry or cardiac output. Use of this device is indicated only in a medically supervised healthcare environment. 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)

Art A. Ciall

Prescription Use ✓
(Per 21 CFR 801.109)

or

Over-The-Counter Use _____