

510(k) Summary
Fukuda Denshi DynaScope Model DS-7000/7000M
Patient Monitor

AUG 29 2008

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: _____.

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- **Contact Person:** Mr. Loran Van Noy
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- **Date Prepared:** June 13, 2008

Device Name

- **Proprietary Name:** Fukuda Denshi DynaScope Model DS-7000/7000M Patient Monitor
- **Common Name** Patient Monitor
- **Classification** MHX – Monitor, Physiological, Patient (with arrhythmia detection or alarms)

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Legally Marketed Device:

Fukuda Denshi DynaScope Model DS-5300 Patient Monitor 510(k) # **K964187**
Fukuda Denshi DynaScope Model DS-7141 Portable Patient Monitor 510(k) #
K040246

In addition, several functions of the DS-7000/7000M Patient Monitor utilize technology incorporated into previously cleared devices and several OEM manufactured modules that have received separate clearance from the FDA as follows:

The DS-LAN II technology was previously cleared in the Fukuda Denshi DS-5800 submission. 510(k) # **K970585**

The Central Station Monitors, which the DS-7000/7000M can be connected, cleared under 510(k) # **K970585, K000746, and K020084.**

The SpO₂ measurement system used in the DS-7000 is the same as that used in the Nellcor Puritan Bennett model "OxiMax N-560 Pulse Oximeter" cleared under 510(k) # **K021090.**

The SpO₂ measurement system used in the DS-7000M is the same as that used in the Masimo Corporation model "Masimo SET RAD 5 Pulse Oximeter" cleared under 510(k) # **K033296.**

The multigas measurement system used in the DS-7000/7000M is the same as that used in the Criticare Systems, Inc. model "8500 Vital Signs Monitor" cleared under 510(k) # **K012059.**

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Description:

The Fukuda Denshi DynaScope Model DS-7000/7000M Patient Monitor is meant to acquire and monitor physiological signals from patients. The system is design to be used in ICU, CCU, OR, ER, or Recovery areas of the hospital or clinic. Patient ages from neonates to adults can all be monitored. Waveforms, numeric and trend data from these patients are available to the clinician on the systems display or may be printed on the system's recorder.

The DS-7000/7000M allows for the monitoring of ECG, heart rate, respiration, non-invasive blood pressure (NIBP), pulse rate, arterial oxygen saturation (SpO₂), pulse wave, temperature, invasive blood pressure (IBP), and cardiac output. By using the option Multigas Unit (MGU-701/MGU-702), the monitoring of carbon dioxide concentration (CO₂), nitrous oxide concentration (N₂O), which utilizes Criticare Systems technology (K012059), oxygen concentration (O₂), and anesthetic agent concentration (AG) are also possible. And, by using the option Unit (HU-71/HU-72/HU-73), blood pressure (up to 6 channels), cardiac output, temperature (up to 3 channels) can be additionally monitored. For the SpO₂ measurement monitoring, the DS-7000 utilizes a Nellcor technology (K021090) and the DS-7000M utilizes a Masimo one (K033296).

The DS-7000/7000M is a self contained monitor which includes a 12.1 inch TFT color LCD display which can display up to 12 waveforms and up to 20 numeric displays. Input operation is performed by the touch screen panel, 5 fixed keys, or infrared remote-control command (optional).

Additional standard features include the DS-LAN II connection, which is a proprietary network system based on an Ethernet LAN (K970585), through either a built in Ethernet LAN or external telemetry transmitter (the Fukuda Denshi DS-5000 series telemetry model HLX-501/561, K980728) connection for connection to the Fukuda Denshi Central Station Monitors, a built- in dot matrix thermal printer that can print up to 3 wave forms simultaneously, and an alarm indicator feature on the top of device that alerts to alarm conditions.

The DS-7000/700M is small and lightweight at 9.0 kg. The physical dimensions of the device are 324mm (W) x 260 mm (H) x 179 mm (D).

The option Multigas Unit (MGU-701/MGU-702) weight is 1.8 kg. The physical dimensions of the device are 248mm (W) x 138 mm (H) x 82 mm (D).

The option Unit (HU-71/HU-72/HU-73) weight is 180g. The physical dimensions of the device are 37mm (W) x 99 mm (H) x 90 mm (D).

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Statement of Intended Use:

The Fukuda Denshi DynaScope Model DS-7000/7000M Patient Monitor provides a simple and reliable method to display and document the continuous hemodynamic, cardiovascular observations that are typically required of critically ill patients. The target populations of the system are adult, pediatric, and neonatal patients, which may be located in a hospital's ICU, CCU, OR, ER, recovery or other critical care area, with the exception of the ST segment and arrhythmia analysis, for which the target populations are adult and pediatric only. The DS-7000/7000M can also be used to follow patients whose treatment requires close observation of specific physiological parameters. These patients may be in a clinic or other healthcare environment under the care of a physician.

The availability of DS-LAN II connection, through either a built in Ethernet LAN or external telemetry transmitter, allows remote monitoring when combined with Fukuda Denshi Central Station Monitors.

Parameters such as ECG, heart rate, respiration, non-invasive blood pressure (NIBP), pulse rate, arterial oxygen saturation (SpO₂), pulse wave, temperature, invasive blood pressure (IBP), cardiac output, carbon dioxide concentration (CO₂), nitrous oxide concentration (N₂O), oxygen concentration (O₂), and anesthetic agent concentration (AG) may be monitored individually or in any grouping required by the clinician.

The DS-7000/7000M is not recommended for home use, when it has not been ordered by a physician.

Technological Characteristics:

The DS-7000/7000M incorporates the identical technology as the predicate devices. The device provides a means with interfacing with a patient, collecting parameter specific physiological data and processing the data for alarm generation, display of numeric values and waveforms at bedside or at a central monitoring station.

The technology characteristics of the DS-7000/7000M 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.

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Testing:

The Fukuda Denshi DynaScope Model DS-7000/7000M Patient Monitor has been subjected to extensive safety, environmental and performance testing. Final testing for the device included various performance test for the device designed to insure that all functional and performance specifications were met. 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.

The DS-7000/7000M has also been tested to assure compliance to the requirement of various published standards including the following:

General safety standards

- UL60601-1: 2006
- IEC60601-1-1: 2000
- IEC60601-1-4: 2000
- IEC60601-1-8: 2003
- ISO 14971:2000+A1:2003

Individual standards

- ANSI/AAMI EC-13: 1992
- ANSI/AAMI EC-53: 1995
- ANSI/AAMI EC-57: 1998/(R)2003
- ANSI/AAMI SP-10: 2002+A1:2003+A2:2006
- IEC60601-2-27:2005
- IEC60601-2-30:1999
- IEC60601-2-34:2000
- IEC60601-2-49:2001
- EN12470-4: 2000
- EN980:2003
- ISO 9919: 2005
- ISO 21647:2004

EMC standards

- IEC 60601-1-2:2001+A1:2004

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Conclusion:

In conclusion, drawing from laboratory testing, validation and risk Analysis, the Fukuda Denshi DynaScope Model DS-7000/7000M Patient Monitor demonstrates that this device is as safe and effective and performs as well or better than the legally marketed predicate devices, the Fukuda Denshi DS-5300 Patient Monitor 510(k) # **K964187**, the Fukuda Denshi DS-7141 Portable Patient Monitor 510(k) # **K040246**, Nellcor Puritan Bennett model "OxiMax N-560 Pulse Oximeter" 510(k) # **K021090**, the Masimo Corporation model "Masimo SET RAD 5 Pulse Oximeter" 510(k) # **K033296**, and the Criticare Systems, Inc. model "8500 Vital Signs Monitor" 510(k) # **K012059**.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 9 - 2008

Fukuda Denshi USA, Inc.
c/o Ms. Susan D. Goldstein-Falk
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, NY 11021

Re: K081891

Trade/Device: Fukuda Denshi DynaScope Model DS-7000/7000M Patient Monitor

Regulation Number: 21 CFR 870.1025

Regulation Name: Arrhythmia Detector and Alarm (including ST-segment measurement and alarm)

Regulatory Class: Class II (two)

Product Code: MHX

Dated: June 30, 2008

Received: July 2, 2008

Dear Ms. Goldstein-Falk:

This letter corrects our substantially equivalent letter of August 29, 2008.

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 (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.

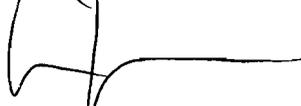
Page 2 - Ms. Susan D. Goldstein-Falk

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 continue 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 (240) 276-0120. 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 from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 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

Indications for Use

510(k) Number (if known): K

Device Name: Fukuda Denshi DynaScope Model DS-7000/7000M Patient Monitor

Indications For Use:

Use of the Fukuda Denshi DynaScope Model DS-7000/7000M Patient Monitor is indicated in those situations where observation of one or more of the following parameters on an individual patient may be required. ECG (waveform, heart rate, ST-Level and ventricular arrhythmias), respiration, non-invasive blood pressure (NIBP), pulse rate, arterial oxygen saturation (SpO₂), pulse wave, temperature, invasive blood pressure (IBP), cardiac output, carbon dioxide concentration (CO₂), nitrous oxide concentration (N₂O), oxygen concentration (O₂), and anesthetic agent concentration (AG). The target populations of the system are adult, pediatric, and neonatal patients with the exception of the ST segment and arrhythmia analysis, for which the target populations are adult and pediatric only. These observations can include an audible and visual alarm if any of these parameters exceed values that are established by the clinician. The observations may include the individual or comparative trending of one or more of these parameters over a period of up to 24 hours. The DS-7000/7000M is indicated in situations where an instantaneous display of waveform, numeric and trended values is desired. The DS-7000/7000M also indicated where a hard copy record of the physiological parameters, the alarms conditions or the trended values may be required.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 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

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510(k) Number K081891