JUN 12 1998

K980979

510(k) Summary
Fukuda Denshi model HC-500
End Tidal CO_2 Module

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 : K980979

Submitter:

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Date Prepared:

March 9, 1998

Device Name:

Proprietary Name:

model HC-500 End Tidal CO_2 Module

Common Name:

$ETCO_2$ Gas Module

Classification Name:

Carbon Dioxide Gas Analyzer (§869.1400)

Legally Marketed Device:

FUKUDA DENSHI model HC-300 End Tidal CO_2 Module 510(k) number K950044. (The HC-500 is an addition to the to the DS-5300, 510(k), K964187.)

Description:

The Fukuda Denshi model HC-500 End Tidal CO_2 Module is a computer controlled medical device. It is designed to non-invasively provide respiration, inspired and expired CO_2 values when used as part of the DS-5300 Patient Monitoring System (K964187). The HC-500 is a module, not a stand alone device. As a module, it will only operate when installed into a DS-5300 bedside patient monitor. The Fukuda Denshi model HC-500 $ETCO_2$ module will function with all NOVAMETRIX main stream sensors.

The safety and efficacy of the HC-500 module has been established through various techniques. Review of the Fukuda Denshi model HC-300 predecessor product's history does not reveal any complaints related to safety and/or effectiveness. There are no reports of adverse effects or reportable incidents for the currently marketed HC-300 $ETCO_2$ product.

Statement of Intended Use:

The Fukuda Denshi model HC-500 End Tidal CO_2 Module is intended to be used to non-invasively monitor inspired and expired CO_2 and respiration rate by trained medical professionals by or on the order of a physician. The Fukuda Denshi model HC-500 End Tidal CO_2 Module will function with all NOVAMETRIX reusable and disposable main stream sensors.

The Fukuda Denshi model HC-500 End Tidal CO_2 Module is intended to be used in all patient populations who are under the care of a physician, within the confines of a health care facility. The intended environment is critical monitoring situations, including ventilator support and anesthesia, where the Fukuda Denshi DS-5300 bedside patient monitor is being utilized with an IB-5006 Input Box.

The Fukuda Denshi model HC-500 End Tidal CO_2 Module is NOT INTENDED FOR HOME USE.

The Fukuda Denshi model HC-500 End Tidal CO_2 Module is intended to be used as part of the Fukuda Denshi DS-5000 series of bedside patient monitoring systems. The HC-500 will not function as a stand alone device.

Comparison to Predicate Device

In summary, the HC-500 module is an updated version of the HC-300 $ETCO_2$ module designed for use in the DS-5000 series of patient monitors. Changes to the system include a reduction in size and weight to meet the requirements of the DS-5000 series modules. Control circuits have been incorporated into a Fukuda Denshi designed CPU. The front end design, as specified by Novametrix Medical Systems, Inc. has been relayed out to DS-5000 series module size specifications. The majority of the changes can be summarized as re-layout of circuits and a reduction in size.

Technological Characteristics

The Fukuda Denshi model HC-500 End Tidal CO_2 Module uses small, light weight main stream sensors, Capnostat II™ or Capnostat III™, manufactured by Novametrix Medical Systems Inc. The sensors employ Novametrix solid state infrared technology. All $ETCO_2$ sensing and calculation algorithms are similar to those used in the HC-300 (K950044) and are the same as those employed by Novametrix Medical Systems Inc.

Control circuits have been incorporated into a Fukuda Denshi designed CPU. The front end design, as specified by Novametrix Medical Systems, Inc. has been relayed out to DS-5000 series module size specifications. The majority of the changes can be summarized as re-layout of circuits and a reduction in size.

No changes to the DS-5300 Patient Monitoring System (K964187) hardware or software were required to accommodate the HC-500.

Testing:

Laboratory testing was conducted to validate and verify that the Fukuda Denshi model HC-500 End Tidal CO_2 Module met all design specifications and was substantially equivalent to the Fukuda Denshi model HC-300 (K950044). End Tidal CO_2 validation and verification testing conducted according to Novametrix Medical Systems Inc. testing protocol

Product testing included 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 the ANSI/AAMI standards ES1-1993, "Safe current limits for electromedical apparatus." Finally, testing was

performed to verify that the design addressed all hazards and 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 and alarms generated by the device may be critical to the proper management of the patient.

The primary 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.
  - Inadequate design of the systems ability to alert the users through audible and visual indicators, can lead to user mistrust and/or inadequate response to the patient's condition. If an inadequate response to the patient's condition should occur the patient may unnecessarily be placed at risk.

The design of the HC-500 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 the Fukuda Denshi model HC-500 End Tidal CO_2 Module 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 HC-300 End Tidal CO_2 Module, K950044

COMPLIANCE CERTIFICATE

I certify that in my capacity as Regulatory Affairs Manager and official FDA correspondent of 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 cardiac monitors and arrhythmia detectors and alarms. I further certify that I am aware of the types of problems to which cardiac monitors and arrhythmia detectors and alarms are susceptible to and that to the best of my knowledge, the attached summary of the types of causes of safety or effectiveness problems about these devices 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 America Corp.

Title

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 1998

Mr. David J. Geraghty
Fukuda Denski USA, Inc.
17725 N.E. 65th Street, Building C
Redmond, WA 98052

Re: K980979
Fukuda Denshi Model HC-500 End Tidal CO_2 Module
Regulatory Class: II (two)
Product Code: 73 CCK
Dated: March 13, 1998
Received: March 17, 1998

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 (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/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Intended Use:

The Fukuda Denshi model HC-500 End Tidal CO_2 Module is intended to be used to non-invasively monitor inspired and end tidal CO_2 and respiration rate by trained medical professionals by or on the order of a physician. The Fukuda Denshi model HC-500 End Tidal CO_2 Module will function with all Novametrix reusable and disposable main stream sensors.

The Fukuda Denshi model HC-500 End Tidal CO_2 Module is intended to be used in an adult, infant and/or neonate patient population who are under the care of a physician, within the confines of a health care facility. The intended environment is critical care monitoring situations, including ventilator support and anesthesia where the Fukuda Denshi model DS-5300 Patient Monitor is being utilized.

The Fukuda Denshi model HC-500 End Tidal CO_2 Module is not intended for home use.

The Fukuda Denshi model HC-500 End Tidal CO_2 Module is intended to be used as part of the Fukuda Denshi DynaScope™ DS-5000 series of bedside patient monitoring systems. The HC-500 will not function as a stand alone device.

Statement of Indications for Use

The Fukuda Denshi model HC-500 End Tidal CO2 Module is indicated in those situation where it is desirable to perform real-time end tidal or inspired carbon dioxide concentration and/or respiration rate monitoring of intubated adult, infant and/or neonate patients who are under the care of a physician, within the confines of a health care facility.

M. Pugh

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K980979

prescriptions use ✓ OTC ____