K043276

DEC 23 2004

Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda S/5™ FM with L-FICU04 and L-FICU04A Software and N-FCREC Module

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

Datex-Ohmeda
86 Pilgrim Road
Needham, MA 02492 USA
Tel: 781-449-8685
Fax: 781-433-1344

NAME OF CONTACT:

Mr. Joel Kent

DATE:

November 23, 2004

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Datex-Ohmeda S/5™ FM with L-FICU04 and L-FICU04A Software and N-FCREC Module

COMMON NAME:

Patient Monitor

CLASSIFICATION NAME:

The following Class II classifications appear applicable:

MHX	Monitor, Physiological,Patient (With Arrhythmia Detection or Alarm)	870.1025
MLD	Monitor, ST segment with Alarm	870.1025
CCK	Analyzer, gas, carbon-dioxide, gaseous-phase	868.1400

The following Class I classifications appear applicable:

DSF	Paper Chart Recorder	870.2810

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Datex-Ohmeda S/5™ FM with L- FICU04 and L- FICU04A software is substantially equivalent to the predicate Datex-Ohmeda S/5™ Compact Critical Care Monitor with L-CICU02 and L-CICU02A software (K022740). The N-F(C)(REC) Extension module used with the FM Monitor allows measuring CO2 (module versions N-FC and N-FCREC) and printing on a recorder chart (module versions N-FREC and N-FCREC). The CO2 measurement of the N-FC(REC) is based on the CO2 measurement of the predicate M-miniC module (K023454). The recorder option is based on the predicate M-REC module, originally cleared in the Datex AS/3 AM Monitor (K933285) and the Datex AS/3 Compact Monitor (K933156) submissions.

DEVICE DESCRIPTION as required by 807.92(a)(4)

The S/5™ FM Monitor with L-FICU04(A) software is a patient monitor, which measures and displays patient physiological parameters in hospital environments. The S/5™ FM uses two types of plug-in measurement modules: Extension module N-F(C)(REC) with CO2 or Recorder option, or both, and Patient side Module E-PSM(P), that measures ECG, impedance respiration , invasive and non-invasive blood pressures, pulse oximetry and temperature. The E-PSM(P) is the subject of a separate 510(k). The miniC unit of the N-FC(REC) Extension module, included in this 510(k) submission, is a side stream gas analyzer. It monitors the Carbon dioxide (CO2) inhaled and exhaled by the patient, by measuring the absorption of CO2 at 4.2-4.3 micrometer using narrow band IR filters. It can also monitor the respiration rate as the frequency of peak (end tidal) CO2 measurements per minute. All concentrations are measured and displayed breath by breath. The MiniC unit of the Extension module is equipped with the mini D-fend water separation system. There are two software options available for the S/5 FM: L-FICU04 and L-FICU04A. The L-FICU04A is equipped with extended arrhythmia analysis capability. Other than arrhythmia analysis capabilities, this software option is identical to the L-FICU04. Commonly, the software is collectively referred to as L-FICU04(A). The E-PSM(P) and N-F(C)(REC) Modules placed in the S/5 FM are automatically recognized by the monitor. Monitoring can begin when patient cables are connected to the module plug-in jacks. The modules perform parameter measurement and minor data processing. The S/5™ FM displays measured parameters in the form of numeric values, waveforms and trends on the screen. Audible and visual alarms are used to indicate patient status. The priority profile of an alarm depends on the parameter. The L-FICU04(A) software performs some module-related tasks like arrhythmia analysis, ST value calculation, heart rate calculation, impedance and respiration rate calculation. All the module communication is also handled in the main software. The S/5™ FM is operated by command board keys. Typically pressing a key results in a pop up menu appearing on the screen. Selections can then be made easily from the menu using a unique ergonomically designed pointing device on the keyboard called a ComWheel™. In addition of the standard command board there is an optional type of keyboard, a hand-held Remote controller (REMCO), which is directly connected to the S/5™ FM via a long cord but provides more flexibility in controlling the monitor while the doctor or nurse is handling other patient care needs. The Recorder is a thermal array printer with which you can print from one to three traces and numerical information with a selectable speed. The S/5™ FM Monitor can be in a stand-alone or networked configuration. If networked, measurement data (parameter-associated numbers, waveforms or trends and patient care documentation) is sent to the network for central viewing of the network, monitor-to-monitor viewing, or for archiving. Software L-FICU04 and L-FICU04A include support for wireless LAN communication between the monitor and S/5 Central station. The networking can thus be hardwired or wireless.

INTENDED USE as required by 807.92(a)(5)

Intended use:
The S/5™ FM with L-FICU04 and L-FICU04A and N-FCREC Module are intended for multiparameter patient monitoring.

Indications for use:
The S/5 FM with L-FICU04 or L-FICU04A software is indicated for monitoring of hemodynamics (including arrhythmia and ST-segment analysis) and respiratory status of all hospital patients.

Extension module N-FCREC (option N-FCREC or N-FC) is indicated for monitoring CO2 and respiration rate of all hospital patients. CO2 measurements are indicated for patients weighing over 5kg (11lbs).

The S/5 FM Monitor and N-F(C)(REC) Extension Module are indicated for use by qualified medical personnel only.

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The Datex-Ohmeda S/5™ FM with L- FICU04 and L- FICU04A software is substantially equivalent to the predicate Datex-Ohmeda S/5™ Compact Critical Care Monitor with L-CICU02 and L-CICU02A software (K022740), as indicated by the similarities discussed below.

The S/5™ FM Monitor is a modular multiparameter patient monitor providing connections to measurement modules, in a similar way as the predicate device. The general construction, indications for use and intended use of the S/5™ FM Monitor are almost the same as for the predicate device (K022740).
The basic model of the monitor is the S/5™ FM with L-FICU04 software. When equipped with extended bedside arrhythmia analysis capability, the monitor is called S/5™ FM with L-FICU04A. The arrhythmia analysis functionality of the S/5™ FM with L-FICU04A is identical to the functionality of the predicate device S/5™ Compact Critical Care Monitor with L-CICU02A software (K022740).
The N-F(C)(REC) Extension module used with the FM Monitor allows measuring CO2 (module versions N-FC and N-FCREC) and printing on a recorder chart (module versions N-FREC and N-FCREC). The CO2 measurement of the N-FC(REC) is based on the CO2 measurement of the predicate M-miniC module (K023454). The recorder option is based on the predicate M-REC module, originally cleared in the Datex AS/3 AM Monitor (K933285) and the Datex AS/3 Compact Monitor (K933156) submissions.
The S/5™ FM Monitor and its predicate device both have the same basic user interface and alarms. They are manufactured using the same processes, and have the same safety and effectiveness, as indicated by the thorough and successful testing of the FM Monitor, documented in this submission.
Based on the above and a detailed analysis in other documentation included in this 510(k) notification and attachments, it is evident that the main features and indications for use of the S/5™ FM Monitor with L- L-FICU04 and L- L-FICU04A software are substantially equivalent in safety and effectiveness compared to the predicate.

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

Datex-Ohmeda S/5™ FM with L-FICU04 and L-FICU04A Software and N-FCREC Module complies with the safety standards below and is therefore safe and effective for the intended use. The device has been thoroughly tested through validation and verification of specifications. Verification of compliance with the following mandatory and voluntary standards has been made:

- IEC 60601-1:1988+ Amdt.:1:1991 + Amdt. 2:1995
- EN 60601-1: 1990 + A1:1993+A2:1995+A13:1996
- CAN/CSA-C22.2 No.601.1-M90 +S1:1994+Amdt. 2:1998
- UL 2601-1:1997
- IEC 60601-2-27:1994/EN 60601-2-27:1994
- IEC 60601-2-30:1999/EN 60601-2-30:2000
- IEC 60601-2-34:2000/EN 60601-2-34:2000
- IEC 60601-2-49:2001/EN 60601-2-49:2001
- ISO 9919:1992/EN865:1997
- EN 1060-1:1995/EN 1060-3:1997
- EN 12470-4:2000
- ISO 9918:1993 / EN 864:1996
- IEC/EN 60601-1-2: 2001
- IEC/EN 60601-1-4: 1996+A1:1999
- ANSI/AAMI ES-1:1993
- ANSI/AAMI EC57:1998
- ANSI/AAMI EC11:1991
- ANSI/AAMI EC13:2002
- IEC 60068-2 (Mech stress tests, Temp and Humidity tests).

CONCLUSION:

The summary above shows that there are no new questions of safety and effectiveness for the Datex-Ohmeda S/5™ FM with L-FICU04 and L-FICU04A Software and N-FCREC Module as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 23 2004

Datex Ohmeda
c/o Mr. Joel C. Kent
Quality and Regulatory Affairs Manager
86 Pilgrim Road
Needham, MA 02492

Re: K043276
Trade Name: Datex-Ohmeda S/5™ FM with L-FICU04 and L-FICU04A Software and Extension module N-FCREC
Regulation Number: 21 CFR 870.1025
Regulation Name: Patient Monitor
Regulatory Class: Class II (two)
Product Code: MHX
Dated: November 24, 2004
Received: November 26, 2004

Dear Mr. Kent:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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 begin 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) 276-0295. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K043276

Device Name: Datex-Ohmeda S/5™ FM with L-FICU04 and L-FICU04A Software and Extension module N-FCREC

Indications for Use:

The S/5 FM with L-FICU04 or L-FICU04A software is indicated for monitoring of hemodynamics (including arrhythmia and ST-segment analysis) and respiratory status of all hospital patients.

Extension module N-FCREC (option N-FCREC or N-FC) is indicated for monitoring CO2 and respiration rate of all hospital patients. CO2 measurements are indicated for patients weighing over 5kg (11lbs).

The S/5 FM Monitor and N-F(C)(REC) Extension Module are indicated for use by qualified medical personnel only.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K043276