JUN 2 6 2001

K011670

Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda Oxygen Saturation Module, M-OSAT and accessories (with TruTrak+ motion correction performance)

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

COMPANY NAME/ADDRESS/PHONE/FAX:

Datex-Ohmeda, Inc.
3 Highwood Drive
Tewksbury, MA 01876
Tel: 978-640-0460
Fax: 978-640-0469

NAME OF CONTACT:

Mr. Joel Kent
FDA Official Correspondent

DATE:

May 26, 2001

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

TRADE NAME:

Datex-Ohmeda Oxygen Saturation Module, M-OSAT and accessories (with TruTrak+ motion correction performance)

COMMON NAME:

Oxygen Saturation Measurement Module, SPO2 Accessories

CLASSIFICATION NAME:

The following Class II classifications appear applicable:

Oximeter (per 21 CFR 870.2700)
Ear Oximeter (per 21 CFR 870.2710)

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

The Datex-Ohmeda Oxygen Saturation Module, M-OSAT and accessories (with TruTrak+ motion correction performance) is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda Oxygen Saturation Module, M-OSAT and accessories (K010463).

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

The Datex-Ohmeda Oxygen Saturation Module, M-OSAT and accessories with TruTrak+ motion correction performance (later referred to as M-OSAT) is a module used to monitor arterial oxygen saturation. The user interface has been implemented in the main software of the following:

- AS/3 Anesthesia Monitor (K933285)
- AS/3 Compact Monitor (K933156) using S-STDxx or S-ARKxx software
- CS/3 Monitors (K974792) using S-ICUxx software
- AS/3 Anesthesia Monitor (K000815) using S-ANE99(A), L-ARK99(A)
- S/5 Compact Anesthesia Monitor (K002478) using S-00A05, S-00A06, L-00A07, L-00A08 software
- S/5 Compact Critical Care Monitor (K002158) using S-00C03, S-00C04 software.

M-OSAT is single-width plug–in parameter module including the arterial oxygen saturation and pulse rate measurements for a modular monitoring system. This module is designed with the following characteristics:

- a single width plug-in module for the S/5 multiparameter monitor
- measuring noninvasive arterial oxygen saturation and pulse rate
- sensor consists of two light wavelengths LEDs and photodetector
- Datex-Ohmeda proprietary SpO2 measurement board Prologue
- an interface board for connecting the measurement board to the monitor
- uses TruTrak+ with motion performance correction technology for measuring noninvasive arterial oxygen saturation during clinical motion

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

The Datex-Ohmeda S/5™ Oxygen Saturation Module, M-OSAT is intended for use with the Datex-Ohmeda modular multiparameter patient monitors for monitoring arterial oxygen saturation of hospitalized patients.

The Datex-Ohmeda S/5™ Oxygen Saturation Module, M-OSAT, and accessories are indicated for monitoring arterial oxygen saturation of hospitalized patients including monitoring during conditions of clinical patient motion. The device is 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 Oxygen Saturation Module, M-OSAT is substantially equivalent in safety and effectiveness to the legally marketed (predicate) M-OSAT Oxygen Saturation Module, (K010463).

The modified M-OSAT module has the following similarities and differences compared to the previously cleared M-OSAT (K010463) predicate device:

- has the same indicated use, except with the addition of the phrase "including monitoring during conditions of clinical patient motion."
- uses the same operating principle, and the same electronic circuitry with the minor exception of a passive electrical component that was added to the Prologue board
- has the same safety and effectiveness
- has the same user interface and alarms, with the exception of the additional messages " <30", and " >250" for Pulse Rate range violations.
- has the same accuracy and measuring range, with the exception of the additional specification 70% - 100% +/-3 digits under clinical motion conditions
- uses the same accessories with the exception of three new OxyTip+ sensors that were added to replace previous devices
- Interface board software was updated
- are manufactured using the same processes

The modified Datex-Ohmeda Oxygen Saturation Module, M-OSAT, has the same intended use and indication for use as the previously cleared device, with the exception noted above.

The M-OSAT units are both intended for use with the Datex-Ohmeda modular multiparameter patient monitors for monitoring arterial oxygen saturation of hospitalized patients. Both are indicated for use by qualified medical personnel only.

The M-OSAT units both have the same user interface and alarm logic as the monitor, with the exception noted above. The data of both modules are receiving and showing on the monitor screen similar. Alarms of both modules have the same alarm menus and alarms can be adjusted equally.

The main differences between M-OSAT and the predicate are primarily due to fact that M-OSAT uses the Datex-Ohmeda "TruTrak+" pulse oximetry technology to improve motion correction performance versus the predicate.

In summary, the Oxygen Saturation Module, M-OSAT, described in this submission is substantially equivalent to the predicate device.

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

The Datex-Ohmeda Oxygen Saturation Module, M-OSAT and accessories (with TruTrak+ motion correction performance) comply with the safety standards below and is therefore safe and effective for the intended use. The device has been thoroughly tested including electrical safety, electromagnetic compatibility, mechanical and environmental tolerance, software 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+ Amendments: A1: 1993, A2: 1995, A13: 1996
- CAN/CSA C22.2 No. 601-1-M90 + S1 (1994)+Amdt2:1998
- UL 2601-1: 1997
- IEC 60601-1-2: 1993
- FDA: Reviewer Guidance for premarket notification submissions: 1993
- IEC 60601-1-4: 1996
- ANSI/AAMI ES1 (1993)
- IEC 601-2-26 (1994)
- ISO 9919: 1992
- EN 865:1997

Conclusion:

The summary above shows that there are no new questions of safety and effectiveness for the Datex-Ohmeda Oxygen Saturation Module, M-OSAT and accessories (with TruTrak+ motion correction performance) as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 6 2001

Mr. Joel Kent
Datex Ohmeda, Inc.
3 Highwood Drive
Tewksbury, MA 01876

Re: K011670
Datex-Ohmeda S/5™ Oxygen Saturation Module, M-OSAT, and accessories
(with TruTrak+ Motion Correction Performance)
Regulation Number: 870.2700
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: May 27, 2001
Received: May 30, 2001

Dear Mr. Kent:

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) 594-4646. 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" (21CFR 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,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011670

Device Name: Datex-Ohmeda S/5™ Oxygen Saturation Module, M-OSAT, and accessories (with TruTrak+ Motion Correction Performance)

The Datex-Ohmeda S/5™ Oxygen Saturation Module, M-OSAT, and accessories are indicated for monitoring arterial oxygen saturation of hospitalized patients including monitoring during conditions of clinical patient motion. The device is indicated for use by qualified medical personnel only.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011670