NOV 6 1998

K983614

Datex-Ohmeda
1315 West Century Drive
Louisville, CO 80027-9560

Telephone
303-666-7001

Customer Service
800-345-2700

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800 345-2755

Website
www.datex-ohmeda.com

5 November 1998

Subjects: 510(k) Summary of Safety and Effectiveness Information for the Datex-Ohmeda 3900/3900P Pulse Oximeters
Proprietary: Datex-Ohmeda 3900/3900P Pulse Oximeters
Common: Oximeter
Classification: Oximeter Class II - 21CFR870.2700 - 74 DQA

The 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 1992.

The Datex-Ohmeda 3900/3900P Pulse Oximeters are substantially equivalent to the following currently marketed device:

- Datex-Ohmeda 3800 Pulse Oximeter.

The Datex-Ohmeda 3900/3900P Pulse Oximeters are noninvasive, arterial oxygen saturation and pulse rate monitors. Both models feature two easy-to-read displays that present patient data and status information. The numeric LEDs (light-emitting diodes) show the SpO_2 and pulse rate values. The LDC (liquid crystal display) shows the plethysmographic waveform, the current Relative Perfusion Index™ pulsatile value (PI_t™), the current high and low SpO_2 and pulse rate limit settings and alarm messages as appropriate. You can choose, through a series of menu options, to send current or trend (SpO_2 or PI_t™ pulsatile value) data to the built-in printer (3900P only) or to a computer. The menu options also include setting the date and time, and labeling individual data records.

Features:

- TruTrak™ data sampling system.
- PerfTrak™ waveform display, an automatic scale of the plethysmographic waveform to provide a relative indication of the sensor site perfusion level.
- Relative Perfusion Index™ pulsatile value (PI_t™) to indicate oximetry signal strength and site perfusion. This value appears on the LCD during monitoring.
- Large SpO2 digital display for clear differentiation from the pulse rate value.
- Backlit and adjustable viewing-angle display for excellent visibility in subdued lighting conditions.
- Direct access to user-selectable high and low alarm limits for SpO2 and pulse rate.
- An audible pulse indicator with an adjustable volume; the automatic pitch modulation reflects changing SpO2 level.
- Visual and audible (adjustable volume) alarms.
- Ability to save user-selected alarm limits and volume settings for use between power-up cycles.
- An alarm-silence feature that silences audible alarms for 120 seconds.
- An all-mute feature that silences audible alarms until deactivated. This ability to mute all alarms can be disabled.

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Features (continued):

- Automatic tiered alarm messages--high, medium, low priorities, and system status.
- Alarm and status-information messages appear on the LCD.
- Language options that display the monitor's screen text and, in most cases, printed or transmitted data in the selected language.
- Short, medium, or long (3, 6, or 12 seconds, respectively) SpO2 response averaging modes.
- Fractional or functional SpO2 calibration modes.
- Automatic storage of up to 24 hours of SpO2, pulse-rate, and PI_t™ pulsatile value data.
- The data in trend memory, along with custom patient labels, alarm limit violations, and time stamps, can be transmitted through the RS-232 connector and to the 3900P printer.
- Viewable SpO2 or PI_t™ pulsatile value trend data.
- Custom patient labels that appear on printer, fax, modem, and serial communication output.
- Two analog output channels, SpO2 and pulse rate, that can be connected to a chart recorder or polysommography machine.
- An automatic self-test and calibration check at start-up. After start up, the oximeter continuously performs background self-tests.
- Rechargeable, sealed, lead-acid battery backup operation, including low battery status reporting.
- Compatibility with several types of Datex-Ohmeda sensors for flexibility

The Datex-Ohmeda 3900/3900P Pulse Oximeters comply with the following standards:

1. CSA C22.2 #601
2. IEC 601-1, Part 1 and Amendments 1 and 2
3. IEC 601-1-1, Part 1
4. IEC 601-1-2, Part 1
5. IEC 601-1-4, Part 1
6. ISO 9919 (1992)
7. UL 2601-1

The Datex-Ohmeda 3800 Pulse Oximeter and the Datex-Ohmeda 3900/3900P Pulse Oximeters are substantially equivalent in design concepts, technologies and materials. The Datex-Ohmeda 3900/3900P Pulse Oximeters were validated through rigorous testing that, in part, support the compliance of the 3900/3900P Pulse Oximeters to the above mentioned standards. Additionally, the software for the Datex-Ohmeda 3900/3900P Pulse Oximeters was developed following a robust software development process and was fully specified and validated by Datex-Ohmeda.

The Datex-Ohmeda 3900/3900P Pulse Oximeters are the next generation in the Datex-Ohmeda 3800 Pulse Oximeter family of products.

Datex-Ohmeda

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 6 1998

Mr. Tom Kroenke
Datex-Ohmeda
Configured Monitors Business Unit
1315 West Century Drive
Louisville, CO 80027-9560

Re: K983684
Datex-Ohmeda 3900/3900P Pulse Oximeter
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: October 29, 1998
Received: October 30, 1998

Dear Mr. Kroenke:

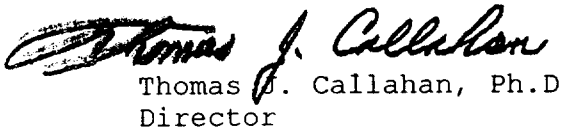
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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) 594-4648. 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/dsma/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

510(k) Number (if known): K983684

Device Name: Datex-Ohmeda 3900/3900P Pulse Oximeters

Indications For Use:

The Datex-Ohmeda 3900/3900P Pulse Oximeters measure arterial oxygen saturation and pulse rate noninvasively using Datex-Ohmeda disposable and reusable finger and ear sensors.

Additionally, the Datex-Ohmeda 3900/3900P Pulse Oximeters measure Relative Perfusion Index™ pulsatile value, which is an indicator of relative perfusion at the sensor site.

US federal and Canadian laws restrict the sale of this device by or on the order of a licensed medical practitioner.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Marie Kramer

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices

510(k) Number: K983684

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21CFR801.109)