SEP - 2 2004

K040831

March 29th, 2004

Subject: 510(k) Summary of Safety and Effectiveness Information for the Datex-Ohmeda TruSat Pulse Oximeter and Accessories

Submitter: Datex-Ohmeda, Inc
1315 West Century Drive
Louisville, CO

Contact: Mr. Scott Light
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Proprietary: Datex-Ohmeda TruSat Pulse Oximeter and Accessories
Common: Oximeter
Classification: Class II, 21 CFR §870.2700, 74 DQA

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

The TruSat substantially equivalent to the FDA cleared and currently marketed Datex-Ohmeda 3800 Series and 3900 Series Pulse Oximeters and Accessories with TruTrak Plus Enhancements (K021955).

The TruSat pulse oximeter is indicated for spot-checking and continuous monitoring of functional oxygen saturation and pulse rate, including monitoring during conditions of clinical patient motion1 or low perfusion. This device is intended for use with adult, pediatric, and neonatal patients in both hospital and non-hospital environments.

The TruSat is designed to comply with the following standards:

- IEC 60601-1: 1988, Am1: 1991, Am2: 95
- IEC 60601-1-1: 2000
- IEC 60601-1-2: 2001
- IEC 60601-1-4: 2000
- IEC 60601-1-8: 2003 (62A/424/FDIS)
- ISO 9919: 1992
- CSA C22.2 #601.1 – M90 (R2001)
- UL 2601-1: 1997

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

The TruSat is the next generation in the Datex-Ohmeda Pulse Oximeter family of products.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 2 2004

Mr. Scott Light
Quality Assurance Manager
Datex-Ohmeda, Incorporated
1315 West Century Drive
Louisville, Colorado 80027-9560

Re: K040831
Trade/Device Name: Datex-Ohmeda TruSat Pulse Oximeter and Accessories, Model
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DPZ
Dated: August 18, 2004
Received: August 19, 2004

Dear Mr. Light:

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 (301) 594-4646. 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,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K

Device Name: Datex-Ohmeda TruSat Pulse Oximeter and Accessories

Indications For Use:

The Datex-Ohmeda TruSat Pulse Oximeter and Accessories is indicated for spot-checking and continuous monitoring of functional oxygen saturation and pulse rate, including monitoring during conditions of clinical patient motion or low perfusion.

These devices are intended for use with adult, pediatric and neonatal patients in both hospital and non-hospital environments.

Prescription Use _XXX_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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