Dräger medical
A Dräger and Siemens Company

K061329

JUL - 7 2006

510(k) SUMMARY
as required per 807.92(c)

1. Submitter's Name and Address: Draeger Medical Systems, Inc.
16 Electronics Avenue
Danvers, MA 01923

Contact Person: Thomas M. McIntosh
Quality Assurance & Regulatory Affairs
Tel: (978) 907-7500
Fax: (978) 907-7734

Date submission was prepared: May 10, 2006

2. Trade Name, Common Name and Classification Name:

A. Trade Name:
Infinity Masimo SET® SpO2 Pod

B. Common Name, Classification Name, Class and Regulation Number:

Common Name	Classification Number	Class	Regulation Number
Oximeter	74DQA	II	870.2700

3. Predicate Device Identification:

Masimo SET® Intellivue Pulse Oximeter Module 510(k) Number – K040259
Masimo SET® Rad-5 Pulse Oximeter 510(k) Number – K033296

4. Device Description:

The Infinity Masimo SET® SpO2 Pod is an addition to Draeger Medical Systems' Infinity patient monitoring series that provides continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for adult, pediatric, and neonatal patients. The Infinity Masimo SET® SpO2 Pod is manufactured by Draeger Medical Systems, Inc. and contains the Masimo SET OEM circuit board with Masimo's SpO2 measurement algorithm.

The pod works as a component of the Infinity patient monitoring series and does not function on its own. The Infinity Masimo SET® SpO2 Pod is connected externally via RS232 using only the X8 connector on the modular monitors Delta/Kappa (USB connector on Gamma series). The Masimo SET® SpO2 pod is powered by the patient monitor.

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An oximetry sensor is attached to a patients finger and one end of a patient cable is connected to the sensor and the other end connected to the Masimo SET® SpO2 Pod. The monitor will begin continuously displaying the patient's pulse rate and SpO2 value. Hi and Low SpO2 and pulse rate alarm limits, alarms, trends and status messages are all controlled by the bedside monitor.

5. Intended Use:

The Infinity Masimo SET® SpO2 Pod is intended for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (measured by an SpO2 sensor). The Infinity Masimo SET® SpO2 Pod is intended for use with Adult, Pediatric, and Neonatal populations. The Infinity Masimo SET® SpO2 Pod is intended to be used by Healthcare Providers, i.e. Physicians, Nurses, and Technicians in hospital and hospital type facilities.

6. Comparison to Predicate Device:

Similar to Masimo SET® Intellivue Pulse Oximeter Module and Masimo SET® Rad-5 Pulse Oximeter, the Infinity Masimo SET® SpO2 Pod provides continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for adult, pediatric, and neonatal patients.

7.Assessment of non-clinical performance data for equivelance:

The Infinity Masimo SET® SpO2 Pod was tested in accordance with applicable standards and internal design control procedures and was determined to be as safe and effective for its intended use as the predicate device.

8. Biocompatability:

Not applicable

9. Sterilization:

Not applicable

10. Standards and Guidances: IEC 60601-1

COMPANY CONFIDENTIAL
Draeger Medical Systems, Inc.
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 7 2006

Mr. Thomas McIntosh
Director, Quality Assurance & Regulatory Affairs
Draeger Medical Systems, Incorporated
16 Electronics Avenue
Danvers, Massachusetts 01923

Re: K061329
Trade/Device Name: Infinity Masimo SET® SpO2 Pod
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: June 5, 2006
Received: June 7, 2006

Dear Mr. McIntosh:

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.

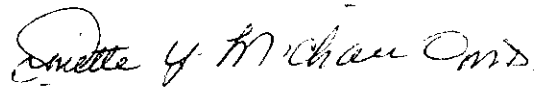
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0115. 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/industry/support/index.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): K061329

Device Name: Infinity Masimo SET® SpO2 Pod

The Infinity Masimo SET® Pod is intended for use under the direct supervision of a licensed healthcare practioner (i.e. . Physicians, Nurses, and Technicians). It is indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (measured by an SpO2 sensor).

The Infinity Masimo SET® SpO2 Pod is indicated for use with adult, pediatric and neonatal patients.

The Infinity Masimo SET® SpO2 Pod and accessories are indicated for use during both motion and non-motion conditions, and for patients who are well or poorly perfused in hospitals and hospital type facilities.

MRI Compatibility Statement: The Infinity Masimo SET® SpO2 Pod is not compatible for use in a MRI magnetic field.

Prescription Use √ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[illegible] 4/9/06

[illegible] Sign-Off)
[illegible]n of Anesthesiology, General Hospital,
[illegible]ion Control, Dental Devices

[illegible] Number: K061329