JUN 16 2005 K 051007

SECTION 2. SUMMARY AND CERTIFICATION

A. 510(k) Summary

Submitter: MITI Corp.

Contact Person: Matthew F. Schmidt, Ph.D.
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Date Prepared: April 19, 2005

Trade Name: MITI Corp. $AccuO_2$ System

Classification Name: and Number: Class II, 21 CFR 868.5905

Product Code: NFB

Predicate Device(s): The $AccuO_2$™ Pulse Oximeter and Demand Oxygen Delivery System is substantially equivalent to the Pulse Dose Series Oxygen Conserving device manufactured by DeVilbiss Health Care, Inc. and the Model 8500A Pulse Oximeter, manufactured by Nonin® Medical, Inc.).

Device Description: The AccuO2 System is a portable, battery-operated system consisting of a proprietary demand oxygen delivery module combined with a commercially available pulse oximeter module[a]. The system is used with a standard nasal cannula and USP portable oxygen. The proprietary software in the AccuO2 demand oxygen delivery module is designed to deliver oxygen on inhalation only and to maintain the patients at an oxygen saturation (SpO2) level of 90% while conserving oxygen.

Intended Use: The $AccuO_2$ System, which provides oxygen therapy on demand based on continuous, non-invasive monitoring of oxygen saturation, is indicated for home use by adult

[a] Pulse oximeter module from Nonin Medical, and is the same as the pulse oximeter module used in the following FDA-cleared devices: Sleep Screen/ApnoeScreen Cardio manufactured by Erich Jaeger GmbH (K021138); Model 9303 Neonatal/Adult Vital Signs Monitor, manufactured by CAS Medical (K982776); and the MTS Option for the ESCORT II Monitor manufactured by Medical Data Electronics (K970763).

COPD patients who are prescribed low-flow (0-3 L/min) supplemental oxygen via nasal cannula and USP portable oxygen.

Functional and Safety Testing:

Functional testing included verification of the AccuO2 System's ability to accurately and reliably detect each inhaled breath, and actuate the valve correctly, as well as verification of the accuracy of the pulse oximeter readings and oxygen amount calculations when used with the system. Clinical testing was conducted to evaluate the ability to maintain patients at or above 90% SpO2 as designed.

In addition, all functional, environmental and safety testing performed on the device demonstrated that it met its performance objectives and complies with applicable FDA guidelines and standards.

Conclusion: The bench studies verified that the AccuO2 System works as designed with back-up safety features functioning correctly. Furthermore, clinical studies demonstrated the AccuO2 maintains patients at or above a pre-set oxygenation level. Clinical studies also showed the AccuO2 does not increase the amount of time the patient spends in an hypoxic state when compared to commercially available devices. Finally, as part of the AccuO2 system, the pulse oximeter functions in a manner equivalent to commercially available pulse oximeters in sensing oxygen levels in patients.

Clinical data demonstrate that the AccuO2 System is substantially equivalent to previously cleared devices and raises no new questions of safety and efficacy over commercially available oxygen conserving systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 16 2005

MITI Corporation
C/O Mr. Jonathan S. Kahan
Hogan & Hartson L.L.P.
555 13th Street, NW
Washington, DC 20004-1109

Re: K051007
Trade/Device Name: $AccuO_2$ System
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: NFB
Dated: April 19, 2005
Received: April 21, 2005

Dear Mr. Kahan:

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) 276-0120. 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 PAGE

Device Name: $AccuO_2$ System

Indications for Use:

The $AccuO_2$ System, which provides oxygen therapy on demand, based on continuous, non-invasive monitoring of oxygen saturation, is indicated for home use by adult Chronic Obstructive Pulmonary Disease (COPD) patients who are prescribed low-flow (0-3 L/min) supplemental oxygen via nasal cannula and USP portable oxygen.

Prescription Use __X____ 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

510(k) Number: K051007