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9. 510(K) SUMMARY

Submission Date: December 14, 2009

Submitter Information:

Company Name:
Or-Nim Medical Ltd.

Company Address:
1 Yodfat Street
Lod, 71291
Israel

JAN 19 2010

Contact Person:
Michal Balberg, PhD
Chief Technical Officer
Or-Nim Medical Ltd.
Tel: +972-8-9282801
Fax: +972-8-9282805
michalb@ornim.com

Device Information:

Trade Name:	CerOx Model 3210
Common Name:	Oximeter/Cerebral Oximeter/Tissue Oximeter
Classification Name:	Oximeter, Tissue Saturation (21 CFR 870.2700)
Product Code:	MUD
Regulatory Class:	II

Predicate Device: The Or-Nim CerOx Model 3210 is a modification of the cleared Or-Nim Pacifica 01 (K073407), which serves as the predicate device.

Device Description: The CerOx Model 3210 uses the well-established principles of near infrared spectroscopy (NIRS) to monitor the concentration of oxygenated hemoglobin relative to the total concentration of hemoglobin in the blood.

CerOx Model 3210 comprises a display and processing unit and probes that are coupled to the patient using a single-use biocompatible adhesive.

When the probes are attached to the patient, the system is operated to monitor the tissue blood oxygen saturation level.

The CerOx Model 3210 can be operated in two modes: Cerebral Mode and Muscle Mode.

Intended Use: The CerOx Model 3210 is intended to monitor oxygen saturation of blood in the body.
Note: the Intended Use of the modified device has not changed as a result of the modifications outlined in this submission.

Indications for Use: The noninvasive Or-Nim CerOx Model 3210 monitor is intended for use as an adjunct monitor of regional hemoglobin oxygen saturation of blood in the brain of an adult. It is also intended for use as an adjunct monitor of hemoglobin oxygen saturation of blood in a region of skeletal muscle tissue beneath the sensor in adults. The prospective clinical value of data from the CerOx monitor has not been demonstrated in disease states. The CerOx monitor should not be used as the sole basis for diagnosis or therapy.
Note: the Indications for Use statement for the modified device has not changed as a result of the modifications outlined in this submission.

Comparison to Predicate Device:

The Or-Nim CerOx Model 3210 represents a modification to the cleared Or-Nim Pacifica 01 (K073407). The original and modified devices have the same intended use, the same indications for use, the same technological characteristics, and are used on the same sites of the body.

Summary of Design Control and Test Activities:

The risk analysis method used to assess the impact of the modifications was Failure Modes, Effects and Criticality Analysis (FMECA). For risks which were identified as a result of the modifications, mitigations were designed and implemented in accordance with the Quality System Regulations. Hardware and software tests were then performed to validate the mitigations.

Conclusions: The results of the design control process and the tests performed on the modified device (CerOx Model 3210) support the conclusion that it remains as safe and effective as, and remains substantially equivalent to, the cleared predicate device (Pacifica 01).

10. STANDARDS DATA REPORT FOR 510(K)S

10.1. FDA Recognized Voluntary Consensus Standards

Both the original Pacifica and the modified CerOx are in compliance with FDA-recognized performance and safety standards. Form 3654 (Appendix H) lists the standards cited and the table attached to it specifies sections to which the CerOx conforms. For each standard, sections other than those listed in the table attached to Form 3654 were deemed Not Applicable.

Testing of acoustic parameters and display was performed in accordance with standards from the American Institute of Ultrasound in Medicine (AIUM) (Table 11.2). Design and testing of the CerOx was performed in accordance with 21 CFR§1040.10 and 21 CFR§1040.11.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Or-Nim Medical, Ltd.
% Michal Balberg, Ph.D.
Chief Technical Officer
1 Yodfat Street
Lod, 71291 Israel

JAN 19 2010

Re: K093923
Trade/Device Name: CerOx Model 3210
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: MUD
Dated: December 17, 2009
Received: December 22, 2009

Dear Dr. Balberg:

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 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

8. STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K093923

Device Name: CerOx Model 3210

Indications for Use:

The noninvasive Or-Nim CerOx Model 3210 monitor is intended for use as an adjunct monitor of regional hemoglobin oxygen saturation of blood in the brain of an adult. It is also intended for use as an adjunct monitor of hemoglobin oxygen saturation of blood in a region of skeletal muscle tissue beneath the sensor in adults. The prospective clinical value of data from the CerOx monitor has not been demonstrated in disease states. The CerOx monitor should not be used as the sole basis for diagnosis or therapy.

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

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093923