NOV 16 2011

Attachment 3

Section 11: 510k Summary

510k Summary K111773

Submitters Name and Address: ReNu Medical, Inc.
9800 Evergreen Way
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Phone: 425-353-1110
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FDA Registration Number: 3034520

Contact Person: L. Bruce Pierson
Chief Operating Officer

Date Summary Prepared: October 5, 2011

Trade or Proprietary Name(s): ReNu Medical Reprocessed OxiMax Sensors: Adult, Pediatric, Infant and Neonate

Common Name: Oximetry Sensors

Classification: Oximeter (21 CFR 870.2700) / NLF

Equivalent Device(s)

K033973 Nellcor Reprocessed Oxisensor II Sensor, Reprocessed OxiMax Sensor
K081927 ReNu Medical Reprocessed Masimo LNCS Adtx, LNCS Pdtx, LNCS Inf and LNCS Neo.
K063661 ReNu Reprocessed Oxisensor D-20 and I-20
K072194 ReNu Reprocessed Oxisensor D-25 and N-25

Device Description:

The ReNu Medical Reprocessed OxiMax Sensors are accessory devices to an oximeter monitoring system. The oxisensor is designed as a transducer for the transmission of electrical signals from the oximeter to the patient and the return of patient modified signals back to the oximeter for analysis and display of patient information. The sensor contains three optical components; two light emitting diodes (LEDs) serve as light sources and one photodiode acting as a light detector LED and sensor are contained in a laminated envelope provided with an adhesive bandage for attachment a patient. A sensor package is attached to a cable terminated in a multi-pin connector that plugs into the oximeter.

Comparison to Predicate

No significant changes or modifications that could significantly affect the models' safety or effectiveness are made to the Max Series models. In particular, no significant changes or modifications in design, material, chemical composition, energy source, or manufacturing process are made. And the intended use of the models – to monitor blood oxygen saturation and pulse rate in humans – remains the same. As such, the ReNu Medical reprocessed Max Series models are not changed or modified from the ReNu Medical reprocessed D-25, N-25, D-20 and I-20 models (which are lawfully marketed under 510(k)s), neither affect the safety or effectiveness of these devices, nor do they change or modify the device's intended use.

Indications for Use

OxiMax Adult: continuous non-invasive arterial oxygen saturation and pulse rate monitoring of patients > 30 kg.

OxiMax Pediatric: continuous non-invasive arterial oxygen saturation and pulse rate monitoring of patients 10 - 50 kg.

OxiMax Infant: continuous non-invasive arterial oxygen saturation and pulse rate monitoring of patients between 3 kg and 20 kg.

OxiMax Neonate: continuous non-invasive arterial oxygen saturation and pulse rate monitoring of patients foot if < 3 kg, or finger if > 40 kg.

Functional and Safety Testing

Reprocessed OxiMax Sensors were tested to demonstrate functional characteristics by bench testing and in vivo clinical studies. High level disinfection process validation testing was performed.

Summary of Non-Clinical Tests

Bench testing was performed to determine pulse rate accuracy using an OxiTest 7 simulator. Varying environmental conditions and physical tests were performed for temperature and humidity.

Summary of Clinical Tests

Clinical studies in vivo were performed on both Adult and Neonate subjects to demonstrate accuracy of SpO_2 in the reprocessed sensors.

Conclusion

Based on an assessment consisting of bench testing and clinical performance data the ReNu Medical Reprocessed Oximetry Sensors function in a manner that are Substantially Equivalent to that of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. L. Bruce Pierson
Chief Operating Officer
ReNu Medical, Incorporated
9800 Evergreen Way
Everett, Washington 98204

NOV 16 2011

Re: K111773
Trade/Device Name: ReNu Reprocessed Nellcor OxiMax Sensors, OxiMax Adult, OxiMax Pediatric, OxiMax Infant, OxiMax Neonate
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: NLF
Dated: November 3, 2011
Received: November 14, 2011

Dear Mr. Pierson:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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/MedicalDevices/Safety /ReportaProblem/default.htm 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 4

1. Statement Indications for Use

Indications for Use
510(k) Number (if known): K111773
Device Name: ReNu Reprocessed Nellcor OxiMax Sensors, OxiMax Adult, OxiMax Pediatric, OxiMax Infant, OxiMax Neonate
Indications For Use:

OxiMax Adult: continuous non-invasive arterial oxygen saturation and pulse rate monitoring of patients > 30 kg.
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OxiMax Neonate: continuous non-invasive arterial oxygen saturation and pulse rate monitoring of patients foot if < 3 kg, or finger if > 40 kg.

Prescription Use XX 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) L Schultz
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: k111773