K063661

Section 13 Premarket Notification

510 (k) Summary

MAY 25 2007

Submitters Name and Address: ReNu Medical
9800 Evergreen Way
Everett, WA ~~98024~~ 98204
Phone: 425-353-1110
Fax: 425-353-9116

FDA Registration Number: 3034520

Contact Person: L. Bruce Pierson
Chief Operating Officer

Date Summary Prepared: August 15, 2006

Trade or Proprietary Name(s): ReNu Medical Reprocessed Nellcor™ D-20 Oxysensor® II, ReNu Medical Reprocessed Nellcor™ I-20 Oxysensor® II

Common Name: Oxisensor

Classification: Oximeter (21 CFR 870.2700)/ NLF

Equivalent Device(s)

The ReNu Medical Reprocessed Nellcor™ D-20 Oxysensor® II and Nellcor™ I-20 Oxysensor® II are substantially equivalent to the Nellcor™ D-20 Oxysensor® II and Nellcor™ I-20 Oxysensor® II (respectively)

Device Description:

The ReNu Medical Reprocessed Nellcor™ D-20 Oxysensor® II and Reprocessed Nellcor™ I-20 Oxysensor® II 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.

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Intended Use

Both the ReNu Medical Reprocessed Nellcor™ D-20 Oxysensor® II and Reprocessed Nellcor™ I-20 Oxysensor® II are intended as single patient use O_2 transducer/accessory sensors for use in conjunction with the Nellcor™ Oximeter system. The Model D-20 is used for infants from 10 to 50 kg. The Model I-20 is used for infants from 3 to 20 Kg. Both sensors are used for non-invasive monitoring of pulse oxygen hemoglobin saturation (SpO_2) and pulse rate.

Technological Characteristics of the ReNu Medical Reprocessed Nellcor™ D-20 Oxysensor® II and Reprocessed Nellcor™ I-20 Oxysensor® II Compared with the Nellcor™ D-20 Oxysensor® II and Nellcor™ I-20 Oxysensor® II

The predicate devices and the ReNu Medical Reprocessed devices contain identical components (LED, photodiode, laminated envelope, cable, and connector.) The means of patient attachment (adhesive bandage) is identical.

Summary of Comparison Tests

Based on an assessment consisting of bench testing, clinical performance data, and non-clinical performance data the ReNu Medical Reprocessed Nellcor™ D-20 Oxysensor® II and Reprocessed Nellcor™ I-20 Oxysensor® II function in a manner that is Substantially Equivalent to that of the predicate devices.

Safety and Standards

The ReNu Medical Reprocessed Nellcor™ D-20 Oxysensor® II and Reprocessed Nellcor™ I-20 Oxysensor® II are designed to meet the following safety standards:

- EN 60601-1
- EN60601-1-2
- Biocompatibility ISO10993-10 1995 EN 30993-1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

MAY 25 2007

Re: K063661
Trade/Device Name: ReNu Reprocessed Nellcor Oxysensor, D-20 and I-20
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: NLF
Dated: May 22, 2007
Received: May 23, 2007

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.

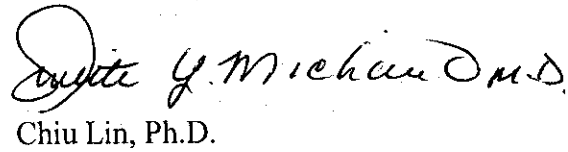
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

510(k) Number (if known): _____

Device Name: ReNu Reprocessed Nellcor D-20 AND I –20 Oxysensor

Indications for Use:

D-20 continuous non-invasive arterial oxygen saturation and pulse rate monitoring of for patients between 10 and 50 kg

I-20: continuous non-invasive arterial oxygen saturation and pulse rate monitoring of for patients between 3 and 20 kg

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

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

Center for Devices and Radiological Health / CDRH

Sign-Off)
ion of Anesthesiology, General Hospital,
ection Control, Dental Devices
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