

Premarket Notification 510(K) Summary

MAR 21 2013

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR§807.92

The assigned 510(k) number is: K113727 (applicant leave blank)

Submission Date: December 6, 2012
Submitter: Shenzhen Med-link Electronics Tech Co., Ltd.
Building 2, HuaFu Ind. Park, HuaWang Road,
LongHua, BaoAn, District 518109 Shenzhen City,
P.R.China

Submitter Contact: Eric Zhan
Regulatory Affairs Specialist
Phone Number: 011 86 (755) 61568827
Fax Number: 011 86 (755) 61120755
E-mail Address: User22@med-linket.com

Device Name/Model: Shenzhen Med-Link Pulse Oximeter Probe
Model S0136J-L

Common Name: Pulse Oximeter Probe

Classification Name: Oximeter
Regulation: 21 CFR §870.2700
Product Code: DQA

Intended Use: Shenzhen Med-link disposable probe, model S0136J-L, is indicated for single patient use when continuous, non-invasive arterial oxygen saturation and pulse rate monitoring are required for adult patients or pediatric patients weighing more than 30 kg. The S0136J-L is contraindicated for use with patients during motion condition.

Predicate Device Reprocessed Nellcor™ D-25 Oximetry Sensor.
K Number: K072194
Manufacturer: ReNu Medical, Inc.

Instrument compatibility Instrument Compatibility: Nellcor N595

Shenzhen Med-link Device Description: Shenzhen Med-link Pulse Oximeter Probes are electro-optical probes which function without skin penetration, electrical contact, or heat transfer. The probes use optical means to determine the light absorption of functional arterial hemoglobin by being

connected between the patient and the patient monitor or oximeter device. The probe contains three optical components: two light emitting diodes (LED) that serve as light sources and one photodiode that acts as a light detector. The LED and photodiode are contained in silicon rubber pads. These SpO₂ probes not made with natural rubber latex.

***Performance Testing:
Biocompatibility
Testing***

Patient contact with materials used in Med-Link Probes were tested in accordance with *ISO 10993-5:1999 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity and ISO 10993-10:2002/Amd1:2006 Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity - Amendment 1*. Test results indicated that the patient contact material were non-toxic, non-sensitizing and non-irritating.

Electrical Safety

Med-Link Probes were tested in accordance with applicable clause of *IEC 60601-1:1988; Amd1:1991; A2:1995, Medical electrical equipment-Part 1: General requirements for safety and ISO 9919:2005, Medical electrical equipment -- Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use*.

Test results indicated that the Probes comply with the applicable clauses of the Standards.

***Electromagnetic
Compatibility Testing***

Med-Link Probes were tested in accordance with applicable clause of *IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests*.

Test results indicated that the Probes comply with the applicable clauses of the Standards.

Pulse Rate Accuracy

Med-Link Probes were tested in accordance with *ISO 9919:2005, Medical electrical equipment -- Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use* to ensure that the probes meet pulse rate accuracy specifications.

Test results indicated that the probes meet the published specifications for pulse rate accuracy over the specified range.

Bench testing

Shenzhen Med-link probe have been conducted the bench testing for the subject device in accordance with *FDA Guidance Document for Pulse Oximeters*. The

bench testing include broad band random vibration, ambient temperature testing, in vitro testing for pulse rate accuracy, shock testing, sinusoidal vibration testing, in vitro testing for SpO₂ accuracy under low perfusion conditions, in vitro testing for pulse rate accuracy under low perfusion conditions and drop testing. The test results indicated that the bench testing has not produced new issue to affect the safety and effectiveness of the device of S0136J-L.

Excessive Temperature

Shenzhen Med-link Probes were tested in accordance with *ISO 9919:2005, Medical electrical equipment -- Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use* to ensure that the probes do not exceed 41°C at the probe-tissue interface at an ambient temperature of 35°C.

Test results indicated that the probes do not exceed 41°C at the probe-tissue interface at an ambient temperature of 35°C.

Clinical

Shenzhen Med-link Probes were clinically tested to validate the performance and accuracy of the probes under controlled hypoxia versus arterial oxygen saturation as determined by co-oximetry. All testing was performed under an institutionally approval protocol with subject informed consent. Med-link Probes clinical study in accordance with *ISO 9919:2005, Medical electrical equipment -- Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use*, *ISO 14155-1:2003, Clinical investigation of medical devices for human subjects — Part 1: General requirements* and *ISO 14155-2, Clinical investigation of medical devices for human subjects —Part 2: Clinical investigation plans*.

Technology Comparison:

Med-Link SpO₂ probe employ the same technological characteristics as the predicate devices to determine arterial oxygen saturation: arterially perfused tissue is illuminated sequentially by two wavelengths of LEDs, and the time varying absorbance of the tissue is measured by a photodetector.

The comparison of the technological characteristics between the subject device and the predicate device in following table.

Table-1 Comparison of the technological characteristics between the subject device and the predicate device

Comparison Item	ReNu Medical Reprocessed Nellcor™ D-25 Oximetry Sensor (K072194)	Shenzhen Med-Link Disposable SpO ₂ Probe, Model S0136J-L
Intended use	D-25 continuous non-invasive arterial oxygen saturation and pulse rate monitoring of patients >30kg, disposable.	Shenzhen Med-link disposable probe, model S0136J-L, is indicated for single patient use when continuous, non-invasive arterial oxygen saturation and pulse rate monitoring are required for adult patients or pediatric patients weighing more than 30 kg. The S0136J-L is contraindicated for use with patients during motion condition.
Measurement Method	2-wavelength Relative Optical Absorption	2-wavelength Relative Optical Absorption
Light Emitting Diodes (LEDs) wavelengths	RED: 660 nm, nominal; IRED:905 nm, nominal;	RED: 660 nm, nominal; IRED:905 nm, nominal;
Signal Detection Method	Photodetector	Photodetector
SpO ₂ Range	1% to 100% SpO ₂	70% to 100% SpO ₂
SpO ₂ Accuracy (70 - 100%) Without Motion	70-100%: ±2% 70-80%:±2% 80-90%:±2% 90-100%:±2%	70-100%: ±3% 70-80%:±3% 80-90%:±2% 90-100%:±2%
Pulse Rate Range	20 to 250 bpm	20 to 250 bpm
Pulse Rate Accuracy	20 to 250 bpm±3digits	20 to 250 bpm±3digits
Shipped sterile	Yes	No
Compliance	<ul style="list-style-type: none"> ● IEC 60601-1:1988, Am1:1991, Am2:1995 ● IEC 60601-1-2:2001 ● ISO 9919:2005 ● ISO 10993-1:2003, ISO 10993-5:1999 and ISO 10993-10:2006 	<ul style="list-style-type: none"> ● IEC 60601-1:1988, Am1:1991, Am2:1995 ● IEC 60601-1-2:2007 ● ISO 9919:2005 ● ISO 10993-1:2003, ISO 10993-5:1999 and ISO 10993-10:2006
Environment Conditions	Storage and Transport (In shipping container) <ul style="list-style-type: none"> ● Temperature: -20 °C to 70 °C ● Atmospheric Pressure: 50 kPa to 106kPa 	Storage and Transport(In shipping container) <ul style="list-style-type: none"> ● Temperature: -10 °C to 40 °C ● Atmospheric Pressure: 86kPa to106kPa
	<ul style="list-style-type: none"> ● Operating Temperature: 5 °C to 40 °C ● Atmospheric Pressure: 50 kPa to 106kPa 	<ul style="list-style-type: none"> ● Operating Temperature: -10 °C to 40 °C ● Atmospheric Pressure: 86kPa to106kPa
	Relative Humidity: 15% to 95% non-condensing	Relative Humidity: 0~80% non-condensing
Cable Length	0.45m	0.9m

Conclusion

Based upon a comparison of devices and performance testing results, Shenzhen Med-link Probes are substantially equivalent to the predicate devices.



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

March 21, 2013

Shenzhen Med-Link Electronics Tech Company, Limited
C/O Ms. Rhonda Alexander, M.S., M.P.A.
Senior Regulatory Specialist
Registrar Corporation
144 Research Drive
HAMPTON VA 23666

Re: K113727

Trade/Device Name: Shenzhen Med-Link Pulse Oximeter Probe
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: March 12, 2013
Received: March 14, 2013

Dear Ms. Alexander:

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,

 Kwame O. Ulmer for

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

Enclosure

Indications for Use

510(k) Number (if known): K 113727

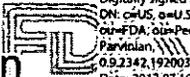
Device Name: Shenzhen Med-Link Pulse Oximeter Probe

Indications of Use: Shenzhen Med-link disposable probe, model S0136J-L, is indicated for single patient use when continuous, non-invasive arterial oxygen saturation and pulse rate monitoring are required for adult patients or pediatric patients weighing more than 30 kg. The S0136J-L is contraindicated for use with patients during motion condition.

Prescription Use AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subparts 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)

Page 1 of 1

Bahram Parvinian 
Digitally signed by Bahram Parvinian
DN: cn=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People, cn=Bahram
Parvinian,
0.9.2342.19200300.100.1.1=1300404336
Date: 2013.03.18 13:36:12 -04'00'

for Lester Schultheis

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: _____

Page 1 of 1