K083010

JUN 10 2009

510(k) Summary

Submission Date:	15 September 2008
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Official Contact:	Thomas Kroenke Principal Consultant Speed To Market, Inc. PO Box 3018 Nederland, CO 80466 USA tkroenke@speedtomarket.net 303 956 4232
Trade Name:	Shenzhen Med-Linket™ Adult SpO2 Finger Sensors including: • Model S0044D-S.
Common Name:	Pulse Oximeter Sensor
Classification Name:	Oximeter
Classification Regulation:	21 CFR §870.2700
Product Code:	DQA

Substantially Equivalent Devices:

Shenzhen Med-Linket™ Model	*Predicate 510(k) Number*	*Predicate Manufacturer / Model*
Adult Silicone Soft Tip SpO2 Sensor, Model S0044D-S (S0012A)	K910852*	CSI 975AD-3 Adult Reusable Pita SpO2 Sensor, 3 foot

* Please note these 510(k) numbers represent monitors containing a pulse oximetry module in which the predicate sensors were included as accessories.

Device Description:

Shenzhen Med-Linket™ Adult SpO2 Finger Sensors (Med-Linket Sensors) are compatible sensors for use with major brands of patient monitors and oximeter devices.

Med-Linket Sensors are electro-optical sensors which function without skin penetration, electrical contact, or heat transfer. The sensors 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 sensor 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.

Intended Use:

Shenzhen Med-Linket™ Adult SpO2 Finger Sensors are indicated for use in continuous, non-invasive arterial oxygen saturation and pulse rate monitoring.

Model S0044D-S is reusable and for patients weighing more than 40 kg.

Shenzhen Med-Linket™ Adult SpO2 Finger Sensors are contraindicated for use on active patients, or during conditions of motion or low perfusion.

Technology Comparison:

Med-Linket Sensors 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.

This method is characteristic of all reusable sensors that are the subject of this submission as well as the predicate devices.

Performance Testing:

Biocompatibility Testing	Patient contact materials used in Med-Linket Sensors were tested in accordance with *ISO 10993-1: 2003, Biological evaluation of medical devices – Part 1: Evaluation and testing* for skin surface-contact, limited-duration devices. Test results indicated that the patient contact materials were non-toxic, non-sensitizing and non-irritating.
Electrical Safety	Med-Linket Sensors were tested in accordance with the applicable clauses of *IEC 60601-1:1988; Am1: 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 sensors comply with the applicable clauses of the Standards.
Electromagnetic Compatibility Testing	Med-Linket Sensors were tested in accordance with the applicable clauses of *IEC 60601-1-2:2001, Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests.* Test results indicated that the sensors comply with the applicable clauses of the Standard.
Pulse Rate Accuracy	Med-Linket Sensors 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 sensors meet pulse rate accuracy specifications. Test results indicated that the sensors meet the published specifications for pulse rate accuracy over the specified range.
Cleaning	Med-Linket Sensors were tested in accordance with internal protocols to ensure that the cleaning instructions do not damage sensor labeling, degrade materials, and that the sensors remain functional after cleaning. Test results indicated that the cleaning instructions do not damage sensor labeling, degrade materials, and that the sensors remain functional after cleaning.

Excessive Temperature	Med-Linket Sensors 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 sensors do not exceed 41° C at the sensor-tissue interface at an ambient temperature of 35 ° C. Test results indicated that the sensors do not exceed 41° C at the sensor-tissue interface at an ambient temperature of 35 ° C.
Environmental	Med-Linket Sensors were tested in accordance with internal protocols to ensure that the operative and storage temperatures, and random vibration do not damage sensor functionality. Test results indicated that the operative and storage temperatures, and random vibration do not damage sensor functionality.
Clinical	Med-Linket Sensors were clinically tested to validate the performance and accuracy of the sensors under controlled hypoxia versus arterial oxygen saturation as determined by co-oximetry. All testing was performed under an institutionally approved protocol with subject informed consent. Test results indicated that the sensors meet the published specifications for accuracy over the specified range.
Conclusion	Based upon a comparison of devices and performance testing results, Med-Linket Sensors are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Shenzhen Med-Link Electronics Tech Company, Limited
C/O Mr. Thomas Kroenke
Principal Consultant
Speed To Market, Incorporated
PO Box 3018
Nederland, Colorado 80466

JUN 10 2009

Re: K083010
Trade/Device Name: Shenzhen Med-Linket™ Adult SpO2 Finger Sensor, Model S0044D-S
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: May 12, 2009
Received: May 13, 2009

Dear Mr. Kroenke:

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/cdrh/comp/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner

Susan Runner, D.D.S., MA
Acting Division 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): K 083010

Device Name: Shenzhen Med-Linket™ Adult SpO2 Finger Sensor, Model S0044D-S.

Indications for Use: The Shenzhen Med-Linket™ Adult SpO2 Finger Sensor is indicated for use in continuous, non-invasive arterial oxygen saturation and pulse rate monitoring.

Model S0044D-S (S0012A) is reusable and for patients weighing more than 40 kg.

The Shenzhen Med-Linket™ Adult SpO2 Finger Sensor is contraindicated for use on active patients, or during conditions of motion or low perfusion.

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: k-083010