K082487

MAR 4 2009

Chapter III 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 9807.92.

The Assigned 510(k) Number is: _____

1. Applicant Device Information

Device Common Name: SpO_2 Pulse Oximeter sensor
Device Trade/Proprietary Name: M-50 Series SpO2 Sensor
Models M-50A;M-50B;M-50C;M-50E;M-50G;M-50H

Classification Information:

(1) **Classification Name:** Oximeter
(2) **Regulation Number:** 870.2700
(3) **Product Code:** DQA
(4) **Class:** II
(5) **Review Panel:** Anesthesiology

2. Submitter Information

Manufacturer Name and Address
Beijing Choice Electronic Technology Co., Ltd.
Room 1127-1128 Building B, Bailangyuan
Fuxing Road, , No. A36
Beijing, China 100039

Contact Person of the Submission
Mr. Chen Lei
Ms. Li Yajing
North Building 3F, No.9 Shuangyuan Road
Badachu Hi-tech Zone, Shijingshan District
Beijing China 100041

3. Predicate Device

M-50A SpO2 Sensor (legally market as the accessory of pulse oximter MD300I@K072825)

Manufactured by:
Beijing Choice Electronic Technology Co., Ltd.
Room 1127-1128 Building B, Bailangyuan
Fuxing Road , No. A36
Beijing, China 100039

4. Device Description

The applicant sensor M-50 Series SpO2 Sensors measure, non-invasively, the arterial oxygen saturation of blood. The measurement method is based on the red and infrared light absorption of hemoglobin and oxyhemoglobin. Light of a red and infrared light source is emitted through human tissue and received by a photodiode.

The measurement is based on the absorption of light, which is emitted through human tissue (for example through the index finger). The light comes from two sources (red LED and infrared LED) with different wavelengths and is received by a photodiode. Out of the different absorption behavior of the red and infrared light a so-called ratio can be calculated. The saturation value is defined by the percentage ratio of the oxygenated hemoglobin [HbO2] to the total amount of hemoglobin [Hb].

SpO2 = [HbO2]/([Hb+[HbO2]]

Those sensors contain a red and infrared light source and a photodiode receiving the non-absorbed red and infrared light. The received signals are forwarded to a measurement device that amplifies the acquired signal and an algorithm that calculates the ratio and converts via a validated calibration table the ratio to a saturation value.

The model M-50A and M-50B sensors are the accessory of legally marketed device MD300I (K072825).

All of the sensors included in applicant M-50 Series SpO2 sensors have the identical materials , electro-optical components and basic technical specification.

The model M-50A,M-50B and M-50E sensor use the same configuration manner as the finger clip. All the clip sensors (M-50A, M-50B and M-50E) composed by two sorts

of material, the enclosure's material of the sensor is ABS, and the material of another part which contact with patient skin, we call that " silica gel cushion", is Medical Silicon

The model M-50C use a sort of configuration manner as binding manner. The M-50C just have single material as the Medical Silicon.

The model M-50G and M-50H use the same configuration manner as the fingertip. Because of the fingertip sensor just have single material as the Medical Silicon, so they are soft.

The applicant sensors are not for implant. Those sensors are not sterile and do not need sterilization or re-sterilization. The device is for prescription. The device does not contain drug or biological product.

The device is electrically operated and the electrical safety and electromagnetic compatibility following IEC 60601-1 and IEC60601-1-2 were conducted.

The device is not software-driven.

All the information about the device performance was according to the FDA guidance.

The Clinical Test Report following ISO 9919:2005, Medical electrical equipment- Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use are conducted.

5. Intended Use

The M-50 Series SpO2 Sensor is intended for spot checking or continuous monitoring of functional arterial oxygen saturation and pulse rate in non-invasive with oximeter equipment..

The M-50A,M-50E and M-50G SpO2 Sensor is intended for adult patients in hospitals, hospital-type facilities, and home environments.

The M-50B and M-50H SpO2 Sensor is intended for pediatric patients in hospitals, hospital-type facilities, and home environments.

The M-50C SpO2 Sensor is intended for adult, pediatric, infant and neonatal patients in hospitals, hospital-type facilities, and home environments.

The BCI3301 and 3303 oximeters will be intended for use with the M-50 Series SpO2

Sensor.

6. Substantially Equivalence Determination

Comparison Analysis

Because of the SpO2 sensor M-50A of M-50 series is accessory of predicate device (MD300I), so they have same sensor aspect between them. The mainly difference is the difference between each sensor in M-50 series SpO2 sensor. Each sensor of M-50 series has same classification information, specification, material and safety and effectiveness. The mainly difference is exhibit as Intended use population and configuration.

The mainly difference of intended use population is the intended use of M-50C, which includes neonate use, for this intended use, we provide the clinical trial report to demonstrate the safety and effectiveness of the product. The result of neonate clinical trial is meet the requirements of FDA Pulse Oximeter Guidance.

The configuration of each SpO2 sensor of M-50 series is another difference, although the appearance and configuration manner are different but the material of each sensor are same.

Conclusion

The applicant device is **Substantially Equivalent (SE)** to the predicate device which is US legally market device. Therefore, the applicant device is determined as safe and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 4 2009

Mr. Chen Lei
Beijing Choice Electronic Technology Company, Limited
Room 1127-1128 Building B, Bailangyuan
Fuxing Road, No. A36
Beijing
China 100039

Re: K082487
Trade/Device Name: M-50 Series SpO2 Sensor, Models M50-A;M-50B;M-50C; M-50E;M-50G,M-50H
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: March 2, 2009
Received: March 2, 2009

Dear Mr. Lei:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small

Sincerely yours,

Ginette Y. Michaud

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): Pending

Device Name: M-50 Series SpO2 Sensor, Models M50-A;M-50B;M-50C;M-50E;M-50G,M-50H

Indications for Use:

The M-50 Series SpO2 Sensor is intended for spot checking or continuous monitoring of functional arterial oxygen saturation and pulse rate in non-invasive with oximeter equipment.

The M-50A, M-50E and M-50G SpO2 Sensor is intended for adult patients in hospitals, hospital-type facilities, and home environments.

The M-50B and M-50H SpO2 Sensor is intended for pediatric patients in hospitals, hospital-type facilities, and home environments.

The M-50C SpO2 Sensor is intended for adult, pediatric, infant and neonatal patients in hospitals, hospital-type facilities, and home environments.

Prescription Use √ (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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anita Y. Mahan D.D.S.

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

510(k) Number: K082487