Section 3 510(k) Summary

As required by 807.97

NOV 10 2008

The assigned 510(k) Number is K082641

1 Basic Information

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Submission Correspondent	Ms. Diana Hong / Mr. Lee Fu Shanghai Mid-Link Business Consulting Co., Ltd Sute 8D, No.19, Lane 999, Zhongshan No.2 Road(S) Shanghai, 200030, China Tel: +86-21-64264467 Fax: 760-466-5084 Email: diana.hong@mid-link.net
Proposed Product	
Trade Name	Fingertip Pulse Oximeter
Model	CMS-50D, CMS-50L and CMS-50DL
Product Code:	DQA
Regulation Number:	21 CFR 870.2700
Device Class:	Class II
Submission Purpose:	Modification to Fingertip Pulse Oximeter CMS-50C cleared in K073454.
Predicate Device:	Fingertip Pulse Oximeter CMS-50C K073454
Device Description	The Fingertip Pulse Oximeter is tiny, and with low power consumption, convenient to use and carry. You just need to put the fingertip into the sensor of the device, the SpO2 value will appear on the screen immediately. In the clinical

	practice, the tolerance is smaller than ±2% in the range from 70% to 99%.
Test Conclusion	Laboratory testing was conducted to validate and verify that the proposed devices met all design specifications, including electrical safety, EMC, specifications.
SE Determination	The proposed device, Fingertip Pulse Oximeter, is substantially equivalent (SE) to the predicate device Fingertip Pulse Oximeter (K073454).

2 Device Description

General Description

The pulse oxygen saturation is the percentage of HbO2 in the total Hb in the blood, so-called the O2 concentration in the blood. It is an important bio-parameter for the respiration. Many of the respiration disease will cause hypoxemia, even damage the patient' s life. As a result, monitoring the SpO2 is indispensable in the clinical rescuing. The traditional method to measure SpO2 is to analyze the sample of the patient' s blood to get the partial pressure of oxygen and calculate the SpO2 by use the blood-gas analyzer. This method is inconvenient and discontinuous. For the purpose of measuring the SpO2 more easily and accurately, our company developed the Fingertip Pulse Oximeter. The device can measure the pulse rate simultaneously.

The Fingertip Pulse Oximeter is tiny, and with low power consumption, convenient to use and carry. You just need to put the fingertip into the sensor of the device, the SpO2 value will appear on the screen immediately. In the clinical practice, the tolerance is smaller than ±2% in the range from 70% to 99%.

The applicant device is not for life-supporting or life-sustaining, not for implant. The device or transducers are not sterile and the transducer is reusable and does not need sterilization or re-sterilization. The device is for prescription. The device does contain drug or biological products

The proposed devices, Fingertip Pulse Oximeter, CMS-50D, CMS-50L and CMS-50DL are modification device to Fingertip Pulse Oximeter, CMS-50C which was cleared in K073454. The proposed devices have same intended use, same design and working principle, same key components (including led, photo detector and medical silicon cushion), same data process module and same specifications with the predicate device. The modifications mainly concern on the display function of the device.

3 Indication for Use

The indications for use of the proposed device Fingertip Pulse Oximeter, CMS-50D, CMS-50L and CMS -50DL are same and identical to the original device CMS-50C.

The indication for use is listed below and an Indication for Use Form is presented in Exhibit A Indication for Use Form per FDA required format.

Indication for Use:

The Fingertip Pulse Oximeter is a non-invasive device intended for the spot-check of oxygen saturation of arterial hemoglobin (SpO_2) and the pulse rate of adult and pediatric patients in home and hospital environments (including clinical use in internist/surgery, anesthesia, intensive care ect.). This device is not intended for continuous monitoring.

4 Testing Summary

Validation tests were conducted to validate the design control activity.

The proposed device, Fingertip Pulse Oximeter CMS-50D, CMS-50L and CMS-50DL were tested in accordance with IEC 60601-1 and IEC 60601-1-2 to evaluate the electrical safety and EMC. A declaration of conformity to IEC 60601-1 and IEC 60601-1-2 is presented in Exhibit E Declaration of Conformity.

The proposed device, Fingertip Pulse Oximeter CMS-50D, CMS-50L and CMS-50DL, 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. A declaration of conformity to ISO is presented in Exhibit E Declaration of Conformity.

In addition, the modification to the original device doesn't cover the intended use, key components and data process unit. Therefore, we believe the clinical test per ISO 9919 Annex EE.4 is not required to be conducted on the modified device.

5 SE comparison conclusion

The subject device has same classification information, same indications and intended use, same design principle, same product design and similar specifications, same effectiveness performance, same safety performance as the predicate device.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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NOV 10 2008

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Shanghai Mid-Link Business Consulting Company, Limited
Suite 8D, No.19, Lane 999, Zhongshan No.2 Road(S)
Shanghai, 200030
CHINA

Re: K082641
Trade/Device Name: Fingertip Pulse Oximeter (CMS-50D, CMS-50L and CMS-50DL)
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: November 3, 2008
Received: November 3, 2008

Dear Ms. Hong:

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) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 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,

Chiu Lin, Ph.D. FOR DR CHIU LIN
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit A Indication for Use Form

510(k) Number:
Device Name: Fingertip Pulse Oximeter (CMS-50D, CMS-50L and CMS-50DL)

Indications for Use:

The Fingertip Pulse Oximeter is a non-invasive device intended for the spot-check of oxygen saturation of arterial hemoglobin (SpO_2) and the pulse rate of adult and pediatric patients in home and hospital environments (including clinical use in internist/surgery, anesthesia, intensive care ect.). This device is not intended for continuous monitoring.

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)

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

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