DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 23, 2015

Contec Medical Systems Co., Ltd.
c/o Ms. Diana Hong
General Manager
Mid-Link Consulting Co., Ltd.
P.O. Box 120-119
Shanghai, 200120
China

Re: K141362
Trade/Device Name: Pulse Oximeter CMS50EW
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: March 18, 2015
Received: March 23, 2015

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. 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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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Dental Devices
Office of Device Evaluation
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141362

Device Name
Pulse Oximeter CMS50EW

Indications for Use *(Describe)*
The Pulse Oximeter CMS50EW is a non-invasive device intended for spot-check or continuous monitoring of non-invasive oxygen saturation of arterial hemoglobin (SpO2) and the pulse rate through the finger of adult patients in home and hospital environments (including clinical use internist/surgery, anesthesia, and intensive care settings). The device is reusable and not intended for out-of-hospital transport use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Tab #1 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K141362

1. Date of Submission: 04/20/2015

2. Sponsor Identification

Contec Medical Systems Co., Ltd
No.112 Qinhuang West Street, Economic & Technical Development Zone,
Qinhuangdao, Hebei, 066004, China.

Establishment Registration Number: 3006979678

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3. Submission Correspondent

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4. Proposed Device Identification

Proposed Device Name: Pulse Oximeter CMS50EW
Proposed Device Model: CMS50EW
Proposed Device Common Name: Pulse Oximeter

Regulatory Information:
Classification Name: Oximeter;
Classification: 2;
Product Code: DQA;
Regulation Number: 870.2700;
Review Panel: Anesthesiology;

Intended Use Statement:

The Pulse Oximeter CMS50EW is a non-invasive device intended for spot-check or continuous monitoring of non-invasive oxygen saturation of arterial hemoglobin (SpO2) and the pulse rate through the finger of adult patients in home and hospital environments (including clinical use internist/surgery, anesthesia, and intensive care settings). The device is reusable and not intended for out-of-hospital transport use.

5. Predicate Device Identification

510(k) Number: K090671
Product Name: Pulse Oximeter CMS50E
Manufacturer: Contec Medical Systems Co., Ltd

6. Device Description

The proposed device, Pulse Oximeter CMS50EW is a battery powered fingertip device, which can display % SpO_2, pulse rate value and pulse strength. It is based on digital blood oxygen technology.

The proposed device is composed of power module, signal acquisition module, control and signal processing module. The power source of it is a built-in rechargeable lithium battery. And it has alarm function, to raise the user's attention for exceeding of physiological limit and device error via visual and audio alarming indicator. And the pulse oximeter can communicate with computer by USB data wire and Bluetooth.

The proposed device, Pulse Oximeter CMS50EW, is a modification to the predicate device, CMS50E, cleared under K090671; the modification is to add the blue tooth functionality, however, the oximetry

technology including the sensor was unchanged.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-1:2005 + CORR.1 (2006) + CORR.2 (2007) + AM1 (2012), Medical Electrical Equipment -- Part 1: General Requirements For Basic Safety And Essential Performance.
- 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.
- ISO 80601-2-61:2011, Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.

In addition, wireless transmission function test, including wireless transmission performance, data integrity, wireless coexistence, and security of wireless data, was conducted per the FDA guidance, *Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and Food and Drug Administration Staff*, issued on January 3, 2007. The test results complied with the acceptance criteria.

8. Clinical Test

Clinical testing was not necessary in this submission to support the device modification because the oximetry technology including the sensor is unchanged from the predicate device.

9. Substantially Equivalent (SE) Conclusion

The following table compares the DEVICE to the predicate device with respect to intended use, technological characteristics and principles of operation, etc.

Table 1 Comparison of Technology Characteristics

Item	Proposed Device	Predicate Device
Product Code	DQA	Same
Regulation No.	21 CFR 870.2700	Same
Class	2	Same
Intended Use	The Pulse Oximeter CMS50EW is a non-invasive device intended for spot-check or continuous monitoring of non-invasive oxygen saturation of arterial hemoglobin	Same

	(SpO2) and the pulse rate through the finger of adult patients in home and hospital environments (including clinical use internist/surgery, anesthesia, and intensive care settings). The device is reusable and not intended for out-of-hospital transport use.	
Features	%SpO2 and PR measurement, Pulse bar, Alarm function, Bluetooth	%SpO2 and PR measurement, Pulse bar, Alarm function, no Bluetooth function.
Principles of operation	An experience formula of data process is established taking use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive Hemoglobin (Hb) and Oxyhemoglobin (HbO_2) in glow & near-infrared zones. Operation principle of the device is: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning & Recording Technology, so that two beams of different wavelength of lights can be focused onto human nail tip through perspective clamp finger-type sensor. Then measured signal can be obtained by a photosensitive element, information acquired through which will be shown on screen through treatment in electronic circuits and microprocessor.	Same
Measurement wavelength	Red: 660nm Infrared: 880nm	Same
SpO_2 range	0%-100%	Same
SpO_2 accuracy	70%~100%:±2% , 0~69%,unspecified	Same
PR measurement range	30bpm~250bpm	Same
PR accuracy	±2bpm or ±2% (select the larger)	Same
Patient Contact Material	Silicone	Same
Electrical Safety	Comply with IEC 60601-1	Same
EMC	Comply with IEC 60601-1-2	Same
Label and Labeling	Meet FDA's Requirements	Same

The proposed device, Pulse Oximeter CMS50EW, is a modification to the predicate device, CMS50E, cleared under K090671; the modification is to add the blue tooth functionality, however, the oximetry technology including the sensor was unchanged.

Based on the comparison above, the proposed device, Pulse Oximeter CMS50EW, is determined to be Substantially Equivalent (SE) to the predicate device, Pulse Oximeter CMS50E (K090671).