Section 3 **510(k) Summary** K090671

As required by 807.97

JUN 11 2009

The assigned 510(k) Number is _____

Sponsor	Contec Medical Systems Co., Ltd No. 24, West Huanghe Road Qinhuangdao, Hebei, 066000, China Mr. Li Xueyong, Quality Manager Tel:+86-335-8015490 Fax: +86-335-8015505 Email: lxyong1011@163.com
Submission Correspondent	Ms. Diana Hong / Mr. Tarzan Wang 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	Pulse Oximeter
Model	CMS-50E
Product Code:	DQA
Regulation Number:	21 CFR 870.2700
Device Class:	Class II
Submission Purpose:	New Device
Predicate Device:	Pm-60 Pulse Oximeter K072581
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.
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 Pm-60 Pulse Oximeter (K072581).
Intended Use/Indication for Use	CMS50E The Pulse Oximeter is a non-invasive device intended for the spot-check or continuously monitor of oxygen saturation of arterial hemoglobin (SpO2) and the pulse rate of adult patients through finger in home and hospital environments (including clinical use in internist/surgery, anesthesia, intensive care etc.). The device is not intended for single use and out-of-hospital transport use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 2009

Contec Medical System Company, Limited
C/O Ms. Diana Hong
General Manager
Shanghai Mid-Link Business Consulting Company, Limited
Suite 8D, Zhongxin Zhongshan Mansion,
No 19, Lane 999,
Zhong Shan, Shanghai
CHINA 200030

Re: K090671
Trade/Device Name: CMS50E Fingertip Pulse Oximeter
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: March 13, 2009
Received: March 13, 2009

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 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/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, D.D.S., M.A.
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: CMS50E Fingertip Pulse Oximeter

Indications for Use:

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

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)

L Schuster

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

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