Exhibit #5 510(k) Summary

JUL 15 2011

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: K103685

1. Date of Submission: June 27, 2011

2. Sponsor
   Beijing Rongrui-Century Science & Technology Co., Ltd.
   Room 105-107, Part 1, XianFeng Building, No 7 KaiTuo Road, ShangDi,
   HaiDian District, Beijing, 100096, P.R.China

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3. Submission Correspondent
   Ms. Diana Hong & Mr. Lee Fu
   Mid-Link Consulting Co., Ltd
   P.O. Box 237-023, Shanghai, 200237, China
   Tel: +86-21-22815850
   Fax: 240-238-7587
   Email: info@mid-link.net

4. Proposed Device Identification

   Proposed Device Name: Pulse Oximeter Sensor (Disposable and Reusable)
   Proposed Device Model: RSA002DN, RSJ002DA, RSJ091DI, RST063CA
   Classification: II
   Product Code: DQA
   Regulation Number: 21 CFR 870.2700
   Review Panel: Anesthesiology

Intended Use Statement:

- The Disposable Pulse Oximeter Sensor is indicated for non-invasive spot checking and/or continuous monitoring of arterial oxygen saturation and pulse rate of the adult or neonatal patients with oximeter equipment in hospitals, hospital-type facilities, and home care environments.

- The Reusable Pulse Oximeter Sensors are indicated for non-invasive spot checking and/or continuous monitoring of arterial oxygen saturation and pulse rate of the adult or pediatric patients with oximeter equipment in hospitals, hospital-type facilities, and home care environments.

5. Predicate Device Identification

Predicate Device 1

510(k) Number: K082487
Product Name: SpO2 Pulse Oximeter Sensor
Manufacturer:
Beijing Choice Electronic Technology Co., Ltd.
Room 1127-1128 Building B, Bailangyuan
Fuxing Road, No. A36
Beijing, China 100039

Predicate Device 2

510(k) Number: K093853
Predicate Device Name: Model 6000CN Sensor
Manufacturer:
Nonin Medical, Inc.
13700 1st Ave. North
Plymouth, MN 55441-5443

6. Device Description

The proposed devices of the Pulse Oximeter Sensors (Disposable and Reusable), are used in conjunction with U.S. legally marketed pulse oximeters, in order to measure, non-invasively, the arterial oxygen saturation of blood.

Table 1 General Description

Model	Type	Intended Population	Matched U.S. Legally Marketed Oximeter and Monitor
RSA002DN	Disposable / Wrapping	Adult (>30kg)	Nellcor N595 (K102891)
		Neonatal (<2kg)	
RSJ002DA	Resuable / Finger Clip	Adult (>30kg)	Nellcor N595 (K102891)
RSJ091DI	Reusable / Finger Clip	Pediatric (3-20kg)	BLT M9000 (K100046)
RST063CA	Reusable / Finger Cot	Adult (>30kg)	BLT M7000 (K100046)

7. Test Conclusion

Bench 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 Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995;
- IEC 60601-1 Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests, 2007
- ISO 9919:2005, Medical electrical equipment-Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.

8. Substantially Equivalent Conclusion

The proposed device, Pulse Oximeter Sensor (Disposable and Reusable), is determined to be Substantially Equivalent (SE) to the predicate devices, SpO2 Pulse Oximeter sensor (K082487) and NONIN 6000CN (K093853), in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Beijing Rongrui-Century Scie. & Tech Company, Limited
C/O Ms. Diana Hong
General Manager
Mid-Consulting Company, Limited
P.O. Box 237-023
Shanghai, China 200237

JUL 15 2011

Re: K103685
Trade/Device Name: Pulse Oximeter Sensor (Disposable and Reusable)
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: June 27, 2011
Received: June 29, 2011

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 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/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 Small Manufacturers, International and Consumer Assistance 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,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

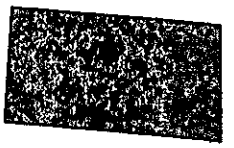

Exhibit #6 Indications for Use

510(k) Number: K103685
Device Name: Pulse Oximeter Sensor (Disposable and Reusable)

Indications for Use:

- The Disposable Pulse Oximeter Sensor is indicated for non-invasive spot checking and/or continuous monitoring of arterial oxygen saturation and pulse rate of the adult or neonatal patients with oximeter equipment in hospitals, hospital-type facilities, and home care environments.

- The Reusable Pulse Oximeter Sensors are indicated for non-invasive spot checking and/or continuous monitoring of arterial oxygen saturation and pulse rate of the adult or pediatric patients with oximeter equipment in hospitals, hospital-type facilities, and home care environments.

☒PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☐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)

Page 1 of 1

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

510(k) Number: K103685