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Exhibit #B 510(k) Summary

JAN 12 2009

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

The assigned 510(k) number is: K082787

Sponsor:	**Beijing Choice Electronic Technology Co., Ltd** Bailangyuan Bldg B 1127-1128, Fuxing road, A36 Beijing, 100039, China Establishment Registration Number: 3005569927 Contact Person: Mr. Chen Lei
Correspondent:	Ms. Diana Hong Mr. Lee Fu Shanghai Mid-Link Business Consulting Co., Ltd Suite 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 Device Information	
Trade Name	Vital Signs Monitor;
Model:	MD500B;
Classification Name:	monitor, physiological, patient;
Product Code:	MWI;
Subsequent Product Codes:	DQA,DXN
Regulation Number:	870.2300;
Device Class:	II
Intended Use:	The MD500B Vital Signs Monitor is intended to be used to monitor physiologic parameters including SpO_2, Pulse Rate (PR) and Non-Invasive Blood Pressure (NIBP) on adult patients in healthcare facilities by clinical physicians or appropriate medical staff under the direction of physicians. It is not intended for transport or home use.
Predicate Device:	VS-800 Vital Signs Monitor K Number: K063055

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Device Description:

The proposed device, MD500B Vital Signs Monitor, is a battery-driven device, which is intended for measuring pulse oxygen saturation (SpO_2), pulse rate (PR), systolic pressure (S) and diastolic pressure (D) on adult.

Testing Conclusion:

Performance testing including clinical and laboratory testing was conducted to validate and verify that the proposed device, MD500B Vital Signs Monitor met all design specifications and was substantially equivalent to the predicate device.

SE Conclusion:

The proposed device, MD500B Vital Signs Monitor is substantially equivalent (SE) to the predicate device, VS-800 Vital Signs Monitor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 12 2009

Beijing Choice Electronic Technology Co., Ltd.
c/o Ms. Diana Hong
Shanghai Mid-Link Business Consulting Co., Ltd.
Suite 8D, No. 19, Lane 999
Zhongshan No.2 Road(S)
Shanghai, 200030, China

Re: K082787
Trade/Device Name: Vital Signs Monitor Model MD500B
Regulation Number: 21 CFR 870.2300
Regulation Name: Patient Physiological Monitor (without arrhythmia detection or alarms)
Regulatory Class: Class II
Product Codes: MWI, DQA, DXN
Dated: January 2, 2009
Received: January 2, 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 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" (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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit #A Indication for Use Statement

510(k) Number: K082787

Device Name: Vital Signs Monitor, MD500B

Indications for Use:

The MD500B Vital Signs Monitor is intended to be used to monitor physiologic parameters including SpO_2, Pulse Rate (PR) and Non-Invasive Blood Pressure (NIBP) on adult patients in healthcare facilities by clinical physicians or appropriate medical staff under the direction of physicians. It is not intended for transport or home 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)

for B Zuckerman

(Division Sign-Off) 1/9/09
Division of Cardiovascular Devices
510(k) Number K082787