K100626

Section III 510(k) Summary

As Required by CFR 870.92

MAY 21 2010

Sponsor	Shenzhen Biocare Electronics Co., Ltd 5/F, Taohuayuan High-Tech Innovation Park, Baoan Shenzhen, Guangdong, 518102, China Mr. Hongbo Zhong Director Tel: +86-755-27960888 Fax: +86-755-27960643 Email: hb-zhong@tom.com
Submission Correspondent	Ms. Diana Hong / Mr. Lee Fu Shanghai Mid-Link Business Consulting Co., Ltd Sute 5D, No.19, Lane 999, Zhongshan No.2 Road(S) Shanghai, 200030, China Tel: +86-21-64264467 Fax: 240-238-7587 Email: diana.hong@mid-link.net
Proposed Product	
Trade Name	Doppler Fetal Heart Rate Detector
Model	FM-200
Product Code:	KNG
Regulation Number:	21 CFR 884.2660
Device Class:	Class II
Submission Purpose:	New Device
Submission Type	Traditional 510(k)
Predicate Device:	Contec Pocket Fetal Doppler K082480
Intended Use	FM-200 Doppler Fetal Heart Rate Detector is a hand-held, battery powered Doppler devices used for detecting fetal heart beats.
Device Description	Doppler fetal heart rate detector is a portable equipment to detect the

	heart rate of fetus in Obstetrics & Gynecology and delivery room. It can also be used at home or in public place for prenatal diagnosis on pregnant women. Doppler fetal heart rate detector is composed of the parts used for ultrasonic signal emitting and receiving, simulating signal processing, fetal heart rate calculation and display control.
Test Conclusion	Laboratory testing was conducted to validate and verify that the proposed devices met all design specifications, including electrical safety, EMC, specification. Results of these tests demonstrate compliance to the requirements of all consensus standards.
SE Determination	The proposed device, Doppler Fetal Heart Rate Detector, is substantially equivalent (SE) to the predicate device Contec Pocket Fetal Doppler (K082480).

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

MAY 21 2010

Shenzhen Biocare Electronics Co., Ltd
% Ms. Diana Hong
Shanghai Mid-Link Business Consulting Co., Ltd
Suit 5D, No. 19, Lane 999, Zhongshan No.2 Road(s)
Shanghai, 200030
CHINA

Re: K100626
Trade/Device Name: Doppler Fetal Heart Rate Detector
Regulation Number: 21 CFR 884.2660
Regulation Name: Fetal ultrasonic monitor and accessories
Regulatory Class: II
Product Code: KNG
Dated: March 3, 2010
Received: March 5, 2010

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 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/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Exhibit #A Indication for Use Form

510(k) Number: K100626
Device Name: Doppler Fetal Heart Rate Detector, FM-200

Indications for Use:
FM-200 Doppler Fetal Heart Rate Detector is a hand-held, battery powered Doppler devices used for detecting fetal heart beats.

Prescription Use __x____ (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 in Vitro Diagnostic Device Evaluation (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K100626