Exhibit #2 510(k) Summary

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

The assigned 510(k) Number: K131941

1. Date of Preparation: 08/19/2013

2. Sponsor Identification

Guangdong Biolight Meditech Co., Ltd
Innovation First Road, Technology Innovation Coast
Zhuhai, Guangdong, 519085, China

Establishment Registration Number: 3007305624

Contact Person: Ms. Liang, Jing
Position: R&D Director
Tel: +86-756-3399967
Fax: +86-756-3399989
Email: liang_j@blt.com.cn

3. Submission Correspondent

Ms. Diana Hong & Mr. Lee Fu
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120, China
Tel: +86-21-22815850
Fax: 240-238-7587
Email: info@mid-link.net

4. Proposed Device Identification

Proposed Device Name: Fetal monitors
Proposed Device Model: F30, F45, F50, F80, F85 and F90

Classification:
Regulation No.: 21 CFR part 884.2740;
Regulation Name: System, Monitoring, Perinatal;
Product Code: HGM;
Device Class: Class II;

Intended Use Statement

The Fetal Monitors are intended for non-invasive monitoring of fetal and maternal physiological parameters during antepartum examination, labor and delivery. They are intended to be used only by trained and qualified personnel in antepartum examination rooms, labor and delivery rooms.

5. Predicate Device Identification

510(k) Number: K100797
Product Name: Edan F9 Express Dual Fetal/Maternal Monitor
Manufacturer: Edan Instrument Inc

6. Device Description

The proposed fetal monitors, including F30, F45, F50, F80, F85 and F90 are intended for providing continuous monitoring, displaying, printing and recording of basic fetal and maternal parameters, including uterine activity (UA), dual fetal heart rate (FHR) and fetal movement (FM), and extended maternal parameters, including electrocardiograph (ECG), non-invasive blood pressure (NIBP) . Pulse Oxygen Saturation (SpO_2) , Pulse Rate (PR), Temperature (TEMP) and Respiration Rate (RESP).

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:

a) IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995.
b) IEC 60601-1-2:2007, Medical Electrical Equipment - Part 1-2: General Requirements for Safety -

Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests.

c) NEMA UD 2-2004 (R2009), Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 3

d) IEC 60601-1-8 Ed. 2:2006-10, Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.

e) ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity;

f) ISO 10993-10:2002 AMD1 2006, Biological Evaluation of Medical Devices – Part 10: Tests for irritation and delayed-type hypersensitivity;

8. Substantially Equivalent (SE) Discussion

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

Table 3-1 Comparison of Technology Characteristics

Item	Proposed Devices	Predicate Devices
Product Code	HGM	HGM
Regulation Number	21 CFR 884.2740	21 CFR 884.2740
Intended Use	The Fetal Monitors are intended for non-invasive monitoring of fetal and maternal physiological parameters during antepartum examination, labor and delivery. They are intended to be used only by trained and qualified personnel in antepartum examination rooms, labor and delivery rooms.	F9 Express fetal & maternal monitor is intended for monitoring physiological parameters of pregnant women during ante-parturn examination, labor and delivery. It is intended to be used only by trained and qualified personnel in antepartum examination rooms, labor and delivery rooms. F9 Express fetal & maternal monitor is intended for providing NonStress testing or fetal monitoring for pregnant women from the 28th week of gestation. In addition, it provides a solution for maternal vital signs monitoring.
Sterile	No	No
Single Use	No	No
Energy Source	AC Power / DC Power	AC Power / DC Power
Safety	Comply with IEC 60601-1	Comply with IEC 60601-1
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2

Acoustic Output		Track 1 Comply with NEMA UD2	Track 1 Comply with NEMA UD2
Alarming		Comply with IEC 60601-1-8	Comply with IEC 60601-1-8
Biocompatibility		No cytotoxicity, irritation and sensitization	No cytotoxicity, irritation and sensitization
Principle of Operation	Fetal Heart Rate	The proposed fetal monitors adopt Pulsed Wave Doppler (PWD). The transducer will emit ultrasonic beam with low energy; Due to the beat of the fetal heart, there will be a relative motion between the fetal heart and ultrasonic beam, which will cause the frequency change of the reflection ultrasonic wave compared with the transmission ultrasonic wave. Fetal heart rate can be calculated based on this frequency change.	The proposed fetal monitors adopt Pulsed Wave Doppler (PWD). The transducer will emit ultrasonic beam with low energy; Due to the beat of the fetal heart, there will be a relative motion between the fetal heart and ultrasonic beam, which will cause the frequency change of the reflection ultrasonic wave compared with the transmission ultrasonic wave. Fetal heart rate can be calculated based on this frequency change.
	Manual Fetal Movement	A kick counter is provided with the proposed fetal monitors. A pregnant woman may count the numbers of movements she feels her fetus make, by kicking the counter. The monitor will record, display and print the number kicked.	A kick counter is provided with the proposed fetal monitors. A pregnant woman may count the numbers of movements she feels her fetus make, by kicking the counter. The monitor will record, display and print the number kicked.
	Automatic Fetal Movement	FM THRESHOLD (Fetal movement threshold): threshold of the occurrence of automatic fetal movement, can be adjusted from 10% to 80%, FM THRESHOLD represents the percentage of fetal activity intensity, when select 10%, a slight variation of the fetus means a fetal movement; while when select 80%, a strong variation of the fetus means a fetal movement, and it is advised to set to 40%-60%. When FM COUNT is set for AUTO, it means in case of automatic fetal movement, the set is effective. Fetal movement: when the FM COUNT is set for AUTO, if the former and later difference of the fetal movement curve value is more than or equal to the set FM threshold, then the system will automatically add up a FM count. When it frozen, the value has no meaning. AFM (fetal movement curve): display or close AFM on the interface. AFM is a yellow curve displayed in TOCO area, which means the energy diagram of fetal movement. It is a kind of	FM THRESHOLD (Fetal movement threshold): threshold of the occurrence of automatic fetal movement, can be adjusted from 10% to 80%, FM THRESHOLD represents the percentage of fetal activity intensity, when select 10%, a slight variation of the fetus means a fetal movement; while when select 80%, a strong variation of the fetus means a fetal movement, and it is advised to set to 40%-60%. When FM COUNT is set for AUTO, it means in case of automatic fetal movement, the set is effective. Fetal movement: when the FM COUNT is set for AUTO, if the former and later difference of the fetal movement curve value is more than or equal to the set FM threshold, then the system will automatically add up a FM count. When it frozen, the value has no meaning. AFM (fetal movement curve): display or

		relative amounts of diagram, which is related to fetal heart rate and fetal heart amplitude. When one of them has changed, can cause fluctuation in the energy diagram.	close AFM on the interface. AFM is a yellow curve displayed in TOCO area, which means the energy diagram of fetal movement. It is a kind of relative amounts of diagram, which is related to fetal heart rate and fetal heart amplitude. When one of them has changed, can cause fluctuation in the energy diagram.
Principle of Operation	Uterine Activity	A pressure-sensitive contraction transducer, called tocodynamometer (TOCO), is employed in the UA measurement. This TOCO sensor has a flat area that is fixed to the skin of a pregnant woman by a band around the belly. The pressure required to flatten a section of the wall correlates with the internal pressure, thereby providing a measurement of it.	A pressure-sensitive contraction transducer, called tocodynamometer (TOCO), is employed in the UA measurement. This TOCO sensor has a flat area that is fixed to the skin of a pregnant woman by a band around the belly. The pressure required to flatten a section of the wall correlates with the internal pressure, thereby providing a measurement of it.
	ECG	Before mechanical systole, the heart firstly produces electrical excitement, which results in biological current, and conducts the current to the body surface through tissue and humour. Different potential changes take place at various parts of the body, thus body-surface potential differences are formed. Record the changing potential differences to form the dynamic curve, i.e. ECG, also called body-surface ECG or regular ECG. Through many electrodes connected with ECG cables, the monitor examines the changes of body-surface potential caused by the heart of patient, observes the ECG activities, records the ECG waveform, and calculates the HR. The monitor can achieve 3-lead and 5-lead and 12-lead monitoring.	Before mechanical systole, the heart firstly produces electrical excitement, which results in biological current, and conducts the current to the body surface through tissue and humour. Different potential changes take place at various parts of the body, thus body-surface potential differences are formed. Record the changing potential differences to form the dynamic curve, i.e. ECG, also called body-surface ECG or regular ECG. Through many electrodes connected with ECG cables, the monitor examines the changes of body-surface potential caused by the heart of patient, observes the ECG activities, records the ECG waveform, and calculates the HR. The monitor can achieve 3-lead and 5-lead and 12-lead monitoring.
	NIBP	The monitor uses the oscillometric method for measuring NIBP. It is applicable for adult, pediatric and neonatal patients. The method of oscillometric indirectly estimates the systolic and diastolic pressures within the blood vessels by measuring the change of the pressure within blood pressure cuff along with the volume of the arteries and calculates the average pressure.	The monitor uses the oscillometric method for measuring NIBP. It is applicable for adult, pediatric and neonatal patients. The method of oscillometric indirectly estimates the systolic and diastolic pressures within the blood vessels by measuring the change of the pressure within blood pressure cuff along with the volume of the arteries and calculates the average pressure.

Principle of Operation	SpO_2	The measurement of oxygen saturation of arterial blood (also known as pulse oxygen saturation, usually shortened as SpO_2) adopts the principles of light spectra and volume tracing. The LED emits lights with two specific wavelengths, which are selectively absorbed by oxygenated hemoglobin and deoxyhemoglobin. The optical receptor measures the changes in the light intensity after the light passes the capillary network and estimates the ratio of oxygenated hemoglobin and the total hemoglobin.	The measurement of oxygen saturation of arterial blood (also known as pulse oxygen saturation, usually shortened as SpO_2) adopts the principles of light spectra and volume tracing. The LED emits lights with two specific wavelengths, which are selectively absorbed by oxygenated hemoglobin and deoxyhemoglobin. The optical receptor measures the changes in the light intensity after the light passes the capillary network and estimates the ratio of oxygenated hemoglobin and the total hemoglobin.
	Temperature	The monitor measures Temperature with Temperature sensors, and it uses the Thermal resistance method.	The monitor measures Temperature with Temperature sensors, and it uses the Thermal resistance method.
	Respiration Rate	For the respiratory measurement (Resp), the monitor measures the thoracic impedance between two ECG electrodes on the patient's chest. Changes in the impedance due to thoracic movement produce the Resp waveform on the monitor screen. The monitor counts the waveform cycles to calculate the respiration rate (RR).	N.A.

9. Substantially Equivalent (SE) Conclusion

The proposed devices and predicate device share same classification information, similar intended use, technical specifications and safety performance.

Therefore, the proposed devices, Fetal Monitors, are determined to be Substantially Equivalent (SE) to the predicate device, as identified above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

May 15, 2014

Guangdong Biolight Meditech Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd.
P.O. Box 120-119
Shanghai 200120
China

Re: K131941
Trade/Device Name: Fetal Monitors
Models: F30, F45, F50, F80, F85 and F90
Regulation Number: 21 CFR§ 884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM
Dated: April 15, 2014
Received: April 16, 2014

Dear Diana 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,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 2 Indications for Use

510(k) Number: K131941
Device Name: Fetal Monitors
Models: F30, F45, F50, F80, F85 and F90

Indications for Use:

The Fetal Monitors are intended for non-invasive monitoring of fetal and maternal physiological parameters during antepartum examination, labor and delivery. They are intended to be used only by trained and qualified personnel in antepartum examination rooms, labor and delivery rooms.

☒PRESCRIPTION USE (Part 21 CFR 801 Subpart D)	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)

Herbert P. Lerner -S
2014.05.15 16:52:12 -04'00'

Diagnostic Ultrasound Indications for Use Form

SYSTEM: Fetal Monitors, F30, F45, F50, F80, F85 and F90

Transducer: Triple sensor (1 MHz, PWD)

Indented Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (track 1 Only)	Specific (Track 1 and Track 3)	A	B	M	PWD	CWD	Color Doppler	Combined (B/M)	Other (specify)
Ophthalimic	Ophthalmic								
Fetal Imaging & Other	Fetal				N				
	Abdominal								
	Intraoperative (specify)								
	Intraoperative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-Cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Comments: