Summary of safety and effectiveness

AUG 2 2012

In accordance with section 513 (1) of the SMDA as defined in 21CFR part 807.92
This summary is submitted to obtain Pre market 510(K) notification

1. Submitter, manufacturer

Bistos Co., Ltd. (Reg Nr. 3006179052)
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2. Contact person, Consultant

Mr. Young Chi / President
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111 Ellison street, Paterson, NJ 07505. U.S.A.
Tel: 973 278 5222 Fax; 201 934 6030
E mail: biomedusa@msn.com

3. Name of Device

Trade name	:	BT-200V Vascular Doppler Hi-dop
Common or usual name	:	Vascular Doppler
Regulation number	:	870.2100
Regulation class	:	II
Product code	:	DPW
Subsequent Product Code		I T X
Classification panel	:	Cardiovascular, Radiology

4. Substantial Equivalence.

K050601 Koven Technology Corp model Smartdop 45 Vascular doppler

Bistos BT-200V Vascular Doppler is substantially equivalent in Intended use, Design, Function, Performing, direction to use, software, Technology/Principle of operation etc, but Bistos BT-200V has no Printing function.

5. Device Description

Bistos' BT-200V is a pocket size Ultrasound Doppler System, 2 MHz Ultrasound Doppler Probe that measure the fetal heart rate and outputs the Fetal Heart sound through built-in Speaker. By measuring fetal heart rate (FHR), they are able to predict fetal well-being. BT-200V irradiates fetal wave to the abdomen of a pregnant women to detect. The Doppler frequency signal and analyze, displays the heart rate in LCD screen. The device also provides the heart sound from the heart of fetus.

4,5.8 MHz Ultrasound Doppler probe that measures the vascular pulse rate and outputs the blood flow sound through built-in speaker. By measuring pulse rate (PR) they are able to check vascular blood flow status.
BT-200V irradiates vascular wave to the patient skin to detect the Doppler frequency signal and analyze to displays the pulse rate on LCD screen. The device also provides the blood flow sound from the patient.

The following probes may be utilized with the BT-200V Vascular doppler:
- 2 MHz for fetal heart rate
- 4 MHz detections of arterial and venous blood flow velocity
- 5 MHz detections of arterial and venous blood flow velocity
- 8 MHz detections of arterial and venous blood flow velocity

6. Indications for use:

The BT-200V detects arterial and venous blood flow in extremities as well as fetal heart sounds. and displays velocity waveform, numerical data and fetal heart rate with heart beat indicator. The BT-200V selection is 2, 4, 5 and 8 MHz.

7. Contra-indications:

None are known at this time.

8. Labeling

Back label, Market promoting leaflet designed by labeling requirement regulation under (21CFR part 801) page 53, 54 of Technical Construction File

9.Biocompatibility test.

BT-200V used same material of patient contacted part as already cleared Biotos BT-200T under K100885 Fetal Doppler, and done Biocompatibility test by NAMSA (North American Science) by FDA guidance Blue Book Memo G95-1 use of ISO 10993 Biological Evaluation of Medical Device part 4, 5, 10.

10. Test Data

BT-200V Vascular Doppler done various Performing, Safety test voluntary and accordance with the guidance for Industry and FDA Staff - Information for Manufacturers seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers. All test report attached

11, Conclusion.

BT-200V Vascular Doppler is substantially equivalent in Intended use Design, Function, Performing, direction to use, software, Technology/Principle of operation as already cleared predicate device K050601 SmartDop 45.
And used same material as already cleared and in marketing Bistos BT-200T under 510K 100885.
So BT-200V Vascular Doppler has no new issues in safety and effectiveness.

End of Summary

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

AUG 2 2012

Bistos CO., LTD
% Mr. Young Chi
President
Bio-Med USA Inc.
111 Ellison Street
PATERSON NJ 07505

Re: K121267
Trade/Device Name: BT-200V Vascular Doppler
Regulation Number: 21 CFR 884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM
Dated: April 23, 2012
Received: April 26, 2012

Dear Mr. Chi:

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,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for use statement

510 (K) number : K121267

Device name : BT-200V Vascular Doppler

Indication for use: The BT-200V Vascular Doppler (Brand Hi-dop) detects arterial and venous blood flow in extremities as well as fetal heart sounds. and displays velocity waveform, numerical data and fetal heart rate with heart beat indicator. The BT-200V selection is 2, 4, 5 and 8 MHz.

Prescription use _____**xx**_____ **or/and Over the Counter use**_____
(Part 21 CFR 801 Sub part D) **(Part 21CFR 801 Sub part C)**

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

510K K121267

Appendix F

Diagnostic Ultrasound Indications For Use Form

Fill out one form for each ultrasound system and each transducer.

- 2Mhz PW DOPPLER FETAL PROBE – MODEL: BT-200V

Intended use: Diagnostic ultrasound imaging or measursing FHR, Pulse Doppler of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal					P					
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Pheperial Vascular										
Lapaloscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments:

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Prescription Use (Per 21 CFR 801.109

(Division Sign-Off)
dIvision and Reproductive, Abdominal,
And Radiological Devices
510(k) Number K121267

BT-200 V Vascular Doppler

Appendix F

Diagnostic Ultrasound Indications For Use Form

Fill out one form for each ultrasound system and each transducer.

- 4Mhz PW DOPPLER FETAL PROBE – MODEL: BT-200V

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Pheperial Vascular					N					
Lapaloscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division and Reproductive, Abdominal, and Radiological Devices

510(k) Number K121267

BT-200 V Vascular Doppler

Appendix F

Diagnostic Ultrasound Indications For Use Form

Fill out one form for each ultrasound system and each transducer.

- 5Mhz PW DOPPLER FETAL PROBE – MODEL: BT-200V

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Pheperial Vascular					N					
Lapaloscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

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Prescription Use (Per 21 CFR 801.109

(Division Sign-Off)
Division and Reproductive, Abdominal, and Radiological Devices
510(k) Number K121267

BT-200 V Vascular Doppler

Appendix F

Diagnostic Ultrasound Indications For Use Form

Fill out one form for each ultrasound system and each transducer.

- 8Mhz PW DOPPLER FETAL PROBE – MODEL: BT-200V

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Pheperial Vascular					N					
Lapaloscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division and Reproductive, Abdominal, and Radiological Devices

510(k) Number K12267