JUL 0 3 2014

Summary of safety and effectiveness K132543

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

Prepared on Sept 20,2013

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2. Preparer / Contact person.

Mr. Young Chi, President.
Bio-Med USA Inc.
27 New England Drive, Ramsey, NJ 07446. USA
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3. Name of Device.

Trade Name : BT-500 Infant Incubator
Common or usual name : Neonatal Incubator
Regulation number/class : 880.5400 / II
Product Code : FMZ
Classification panel : General Hospital

4. Substantial Equivalence

K102710 Atom Infant incubator model 102, Atom Medical Inc

Bistos BT-500 infant incubator is substantially equivalent in Intended Use, Design, Function, Performing, Direction to use, software, Technology etc to Predicate device.

5. Device Description.

BT-500 Infant Incubator consists of Hood, Control Box, LCD external monitor and main body with stand (optional), This device incorporates two sensors to control Humidity, and Temperature inside the Hood and monitors the Air Conditions, and controls Circulation with proper temperature.
Also Heater is equipped inside of the hood to control the Skin Temperature of Infant at a fixed level as measured by the skin probe and showing, measuring and graphing the humidity, Air Temperature, Skin Temperature, Weight and SpO2

This Incubator is provided with function to control the infant's skin temperature.

6. Intended use.

Bistos' BT-500 is a Infant Incubator and intended to keep Premature Neonate infants in a warm environment in the hood for Neonatal hypothermia, Observation and Examination in newborn nurseries.

BT-500 provides Heat and Air in a controlled manner to neonates or premature infants who are unable to thermo- regulate on their own physiology.

BT-500 is not intended for transport.

7 Labeling

Back label, Market promoting leaflet designed by labeling requirement regulation under (21CFR part 801) is on Technical Construction File.

8.Biocompatibility test.

BT-500 used same material of patient contacted part as already cleared Neo-Servo under K102710, 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.

9. Test Data

BT-500 Infant Incubator done various Performing, Safety test voluntary and accordance with the guidance for Industry and FDA Staff -Neonatal and Neonatal Transport Incubator Premarket notifications., and all test report attached

10, Conclusion.

BT-500 Infant Incubator is substantially equivalent in Intended use Design, Function, Performing, direction to use, software, Technology/Principle of operation as already cleared predicate device K102710 model 102.

So, BT-500 Infant Incubator 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 Center - WO66-G609
Silver Spring, MD 20993-0002

July 3, 2014

Bistos Company, Limited
C/O Mr.Young Chi
Bio-Med USA, Incorporated
27 New England Drive
Ramsey, New Jersey 07446

Re: K132543
Trade/Device Name: BT-500 Infant Incubator
Regulation Number: 21 CFR 880.5400
Regulation Name: Neonatal incubator
Regulatory Class: Class II
Product Code: FMZ
Dated: June 24, 2014
Received: June 26, 2014

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. 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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Mary S. Runner -S

Erin Keith, M.S.
Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K132543

Device Name
BT-500 Infant Incubator

Indications for Use *(Describe)*
Bisto's BT-500 is a Infant Incubator and intended to keep Premature neonate infants in a warm environment in the hood for Neonatal hypothermia, Observation and Examination in newborn nurseries.

BT-500 provides Heat and Air in a controlled manner to neonates or premature infants who are unable to thermo-regulate on their own physiology.

BT-500 is not intended for transport.

Type of Use *(Select one or both, as applicable)*

☒ 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 A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Digitally signed by Richard C. Chapman -S
Date: 2014.07.03 11:54:25 -04'00'

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