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

September 1, 2016

Bistos Co., Ltd.
% Dave Kim
President
Mtech Group
8310 Buffalo Speedway
Houston, TX 77025

Re: K160274
Trade/Device Name: Hi Bebe^{plus,} model BT-100
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: July 21, 2016
Received: July 22, 2016

Dear Dave Kim:

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" (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 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,

For Division

Douglas Silverstein -S
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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

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.*

51O(k) Number *(if known)*
K160274

Device Name

Hi bebe^{plus}, model BT-100

Indications for Use *(Describe)*

The Hi bebe^{plus}, model BT-100, electric breast pump is intended to be used by lactating women for expressing and collecting breast milk. It is intended for a single user.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

K160274

This summary of 510(k) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date 510k summary prepared: August 31, 2016

I. SUBMITTER

Submitter's Name	Bistos Co., Ltd.
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II. DEVICE

Trade/proprietary Name	Hi bebe plus
Model No.	BT-100
Common or Usual Name	Electric Breast Pump
Regulation Name	Powered Breast Pump
Regulation Number	21 CFR 884.5160
Product Code	HGX: pump, breast, powered
Regulatory Class	Class II
Over the Counter Use	

III. PREDICATE DEVICE

Primary Manufacturer	Medela Ag
Device Name	Freestyle Deluxe, Freestyle Solution Set, Freestyle Basic, Freestyle Motor Warranty
510(k) Number	K150499
Regulation Name	Powered Breast Pump
Regulation Number	21 CFR 884.5160 (Product Code: HGX)
Regulatory Class	Class II
Over the Counter Use	

IV. DEVICE DESCRIPTION

The Hi bebe^{plus}, model BT-100, is an electrically powered, software-controlled breast pump intended to express and collect milk from the breast of lactating women. The breast pump system is comprised of a motor unit and pump kit including tubing..

The pump is intended to be used by a single user. The user has the option to pump breast milk from a single breast (single pumping) or from both breasts (double pumping). The Hi bebe^{plus}, model BT-100 also includes back flow protection and it is powered by a 12V DC adaptor or rechargeable lithium battery.

The Hi bebe^{plus}, model BT-100 has two operating functions: basic massage/expression function and memory function to save the operating sequence. The Hi bebe^{plus}, model BT-100, is capable of providing vacuum levels from 32-227 mmHg with cycling rates up to 63 cycles per minute.

V. INDICATIONS FOR USE:

The Hi bebe^{plus}, model BT-100, electric breast pump is intended to be used by lactating women for expressing and collecting breast milk. It is intended for a single user.

VI. PREDICATE COMPARISON

Device name	**Hi bebe ^{plus} BT-100**	**Freestyle® Breast pump** (K150499)
Indication for use	The Hi bebe^{plus}, model BT-100, electric breast pump is intended to be used by lactating women for expressing and collecting breast milk. It is intended for a single user.	Freestyle® is a powered breast pump to be used by lactating women to express and collect milk form their breasts. The Freestyle® is intended for a single user
Intended Use	Express and collect milk	Express and collect milk

Single User Device	Yes	Yes
Environment of Use	Home	Home
Prescription Designation	OTC	OTC
User Control	On-off switch Vacuum /Cycle Up Vacuum /Cycle Down Change Operation Mode	On-off switch Vacuum/Cycle adjustment control
Visual Indicator	LCD display	LCD display
Pumping options	Single or Double pumping	Single or Double pumping
Power Supply	Li-Ion battery or AC adaptor provided 100V-240V, 50/60 Hz	Li-Ion battery or AC adaptor provided
Adjustable Vacuum (expression)	32 - 227 mmHg ±10%	45-245 mmHg
Maximum Vacuum	250 mmHg	270 mmHg
Cycles per minute (expression)	27 - 63 ±5%	49.8 - 81.6
Suction Settings	10	9
Adjustable Suction Levels	Yes	Yes
Mode change	Yes	Yes
Cycling Control Mechanism	Microcontroller	Microcontroller
Back Flow Protection	Yes	Yes
Patient Contact Material	Funnel made of PP	PP

The Hi bebe^{plus}, model BT-100 and the predicate device do not have identical indication for use statements; however, they have the same intended use (expressing and collecting milk from the breasts of lactating women).

In addition, there are differences in the device technological characteristics. The predicate device has 9 adjustable suction levels while the subject device has 10 adjustable suction levels. Also, the predicate device and subject device have different suction strengths and cycle speed ranges. These differences do not raise different questions of safety as compared to the predicate device. The suction levels both allow users to adjust the suction strength.

VII. SUMMARY OF NON-CLINICAL TESTS

Hi bebe^{plus} BT-100 complies with voluntary standards for biocompatibility (in vitro cytotoxicity, irritation and sensitization testing), electrical safety, EMC testing, and use in the home healthcare environment. The following data were provided to support the substantial equivalence determination:

Biocompatibility:
Testing was conducted in accordance with AAMI / ANSI / ISO 10993-5:2009/(R) 2014, Biological Evaluation of Medical Devices-- Part 5: Tests for In Vitro Cytotoxicity (L929 Assay) and AAMI / ANSI / ISO 10993-10:2010, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization. (Vaginal Irritation and Guinea Pig Maximization Sensitization)

Electrical Safety:
Testing was conducted in accordance with AAMI ANSI ES60601-1:2005/(R)2012 and A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) and IEC 60601-1-11:2015 Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance –Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

Electromagnetic Compatibility:
Testing was conducted in accordance with IEC 60601-1-2:2007 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests

Software:
Software verification and validation testing as recommended in FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." (May 11, 2005)

FDA Guidance Document, Design Considerations for Devices Intended for Home Use, issued November 24, 2014 was also used to address home-use considerations.

Performance testing was conducted to show that the device meets its design requirements and performs as intended. The specifications were met for:

- Cycle Speed
- Suction Pressure
- Battery Operating Time
- Battery Recharging Time
- Operating life

These tests were conducted under conditions of single and double pumping mode and for the varying power sources (e.g., AC/DC power vs. battery power).

VIII. SUMMARY OF CLINICAL TESTS

Clinical testing was not required to demonstrate the substantial equivalence of the Hi bebe^{plus}, model BT-100 electric breast pump to its predicate device.

IX. CONCLUSIONS

Based on the information above, Hi bebe^{plus}, model BT-100 electrical breast pump is substantially equivalent to the predicate device.