February 10, 2021

Bistos Co., Ltd.
% Dave Kim
Regulatory Affairs
Mtech Group
7707 Fannin St. Ste 200
Houston, Texas 77054

Re: K200675
Trade/Device Name: Hi bebe^{super} (Models BT-150S and BT-150L)
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: January 7, 2021
Received: January 11, 2021

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For
Monica D. Garcia, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K200675

Device Name

Hi bebe super (Models BT-150S and BT-150L)

Indications for Use *(Describe)*

Hi bebe super (Models BT-150S and BT-150L) 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.

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510(k) Summary
K200675

I. SUBMITTER INFORMATION

Submitter's Name	Bistos Co., Ltd.
Submitter's Address	7th Fl. A Bldg., Woolim Lions Valley 5-cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea (Zip. 13201)
Submitter's Telephone	+82 (31) 7500340
Contact person	Hyesun Jeong (hsjeong@bistos.co.kr) / RA Manager
Official Correspondent	Dave Kim (davekim@mtech-inc.net)
Address	7707 Fannin St. Ste 200, Houston, TX 77054
Telephone	+713-467-2607

Date 510k summary prepared: February 8, 2021

II. DEVICE INFORMATION

Trade/proprietary Name	Hi bebe^{Super} (Models BT-150S and BT-150L)
Common Name	Powered Breast Pump
Regulation Name	Powered Breast Pump
Regulation Number	21 CFR 884.5160
Product Code	HGX (pump, breast, powered)
Regulatory Class	Class II

III. PREDICATE DEVICE INFORMAION

Trade/proprietary Name	Hi bebe^{plus}
Model No.	BT-100
510(k) number	K160274

The predicate device has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

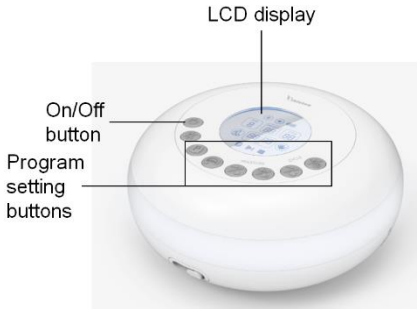
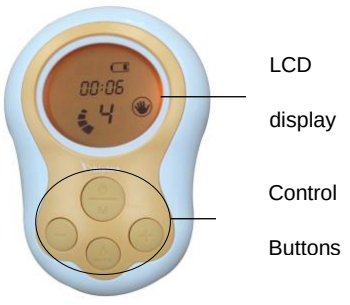
Hi bebe^{Super} are powered breast pumps that are modified versions of the predicate device, K160274. The pumps are intended to express and collect milk from the breast of lactating women and are only to be used by a single user. The user has the option to pump breast milk from a single breast (single pumping) or from both breasts (double pumping). All patient-contacting and breast milk-contacting materials are identical to the predicate device.

Hi bebe^{super} includes two models, BT-150L and BT-150S. BT-150L includes a nursing lamp option, which is not available for BT-150S. Both models are comprised of a motor unit and accessories. The pumps are powered by rechargeable lithium ion batteries (7.4 V Li-ion polymer, 2200 mA) and are software-controlled. The Hi bebe^{Super} breast pumps have two operating modes: massage mode and expression mode. The subject device also includes backflow protection feature to prevent milk from contacting the pump during use. For accessories, a 32 mm size funnel is added in addition to 21/24/27 mm.

V. INDICATIONS FOR USE:

Hi bebe^{Super} (Models BT-150S and BT-150L) is intended to be used by lactating women for expressing and collecting breast milk. It is intended for a single user.

VI. COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS

Device	Hi bebe^{super} K200675	Hi bebe^{plus} K160274
Model No.	BT-150S and BT-150L	BT-100
Manufacturer	Bistos Co., Ltd.	Bistos Co., Ltd.
Indications for use	Hi bebe^{Super} (Models BT-150S and BT-150L) is intended to be used by lactating women for expressing and collecting breast milk. It is intended for a single user	The Hi bebe^{plus}, model BT-100, electric breast pump is intended to be used by lactating women for expressing and collecting breast milk.
Use environment	Home, OTC	Home, OTC
Design		
Visual Indicator	Liquid-crystal display	Liquid-crystal display

User control	Power Memory Lamp brightness Mode change Decrease vacuum Increase vacuum Decrease speed Increase speed	Power and memory Decrease speed/vacuum Increase speed/vacuum Mode change
Accessories	1. Funnel (21/24/27/32 mm) 2. Funnel Block 3. Funnel cap 4. Diaphragm Top, Diaphragm and Diaphragm Bottom 5. Air tube and air tube connector 6. Nipple 7. Bottle 8. Bottle cap 9. Bottle cover and bottle disc.	1. Funnel (21/24/27 mm) 2. Funnel Block 3. Funnel cap 4. Diaphragm Top, Diaphragm and Diaphragm Bottom 5. Air tube and air tube connector 6. Nipple 7. Bottle 8. Bottle cap 9. Bottle cover and bottle disc.
Power	Battery power only: 7.4V Li-ion Polymer 2200 mA Operating time: 120 min. Charging time: 150 min.	1. AC adaptor: 100-240 Vac, 50/60 Hz, 0.3 A 2. Battery: 7.4V Li-ion Polymer 900 mA Operating time: 150 min. Charging time: 90 min.
Maximum vacuum Unit: mmHg	Approx. -290 mmHg	Approx. -250 mmHg
Cycle speed in expression mode	35/40/45/50/55/60 Cycle/Min.	27 to 63 Cycle/Min.
Cycle speed in massage mode	70/80/90 Cycle/Min.	65 Cycle/Min.
Adjustable	6 Steps (Expression mode) /	1 Step (Expression mode)

Cycle Levels	3 Steps (Massage mode) of each suction level	of each suction level
Vacuum range-(mmHg)	Single pumping: • Massage mode: -50 to -230mmHg ± 20% • Expression mode: -50 to -250mmHg ± 20% Double pumping: • Massage mode: -30 to -150mmHg ± 20% • Expression mode: -30 to -200 mmHg ± 20%	Single pumping: • Massage mode: -49 to -110mmHg • Expression mode: -50 to -227mmHg Double pumping: • Massage mode: -27 to -64mmHg • Expression mode: -35 to -165mmHg
Adjustable Suction Levels	16 levels	10 levels
Overflow protection	Diaphragm construction acts as a media separation and prevents milk from going into the pump in case of a milk overflow into the vacuum tubes.	Diaphragm construction acts as a media separation and prevents milk from going into the pump in case of a milk overflow into the vacuum tubes.
Nursing Night lamp	Only applicable to BT-150L	No

The subject and predicate device do not have identical indications for use statements; however, they do have the same intended use, i.e., for collection of breast milk from the breasts of lactating women.

The subject and predicate device have different technological features, including the user interface, pump, vacuum range, cycle speed/range, and power sources. These technological differences do not raise different questions of safety and effectiveness.

VII. SUMMARY OF NON-CLINICAL TESTS

Hi bebe^{super} (Models BT-150S and BT-150L) represent modified versions of the predicate Hi bebe^{plus} (K160274). Performance testing summarized below was conducted to address identified risks associated with the modifications made to the prior cleared device. Other non-clinical testing (i.e., biocompatibility testing of patient-contacting materials and reprocessing of reusable components) rely on information/testing provided in the predicate submission as they were not impacted by the device modifications made.

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 60601-1-2:2014 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 were conducted as recommended in the 2005 FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as Moderate level of concern.

Performance testing was conducted to show that the device meets its design requirements and performs as intended. The performance tests include:

- Vacuum testing in each mode and cycle to demonstrate that devices meet mode/cycle specifications
- Backflow protection
- Battery indicator/operating time
- Battery charging time
- Use-life

VIII. CONCLUSIONS

The performance testing described above demonstrates that the subject devices are as safe and effective as the predicate device and support a determination of substantial equivalence.