September 25, 2025

Bistos Co., Ltd.
Hye Jeong Kim
Primary Correspondent
7th Fl., A Bldg., Woolim Lions Valley 5-cha,
302 Galmachi-ro, Jungwon-gu
Seongnam-si, Gyeonggi-do 13201
KOREA, South

Re: K251512
Trade/Device Name: Hi bebe^{super} (BT-150B)
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: August 28, 2025
Received: August 28, 2025

Dear Hye Jeong 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Monica D. Garcia -S

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251512

Device Name
Hi bebe super (model: BT-150B)

Indications for Use *(Describe)*
Hi bebe super (BT-150B) 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

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

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. 13201
Submitter's Telephone	Tel: +82 31 750 0340 Fax: +82 31 750 0344
Contact Person	Ms. Hyejeong Kim (hjkim@bistos.co.kr) / RA
Date Prepared	September 24, 2025

II. DEVICE INFORMATION

Trade/proprietary Name	Hi bebe^{super} (BT-150B)
Model No.	BT-150B
Common Name	Powered breast pump
Regulation Name	Powered Breast Pump
Regulation Number	21 CFR 884.5160
Product Code	HGX (pump, breast, powered)
Classification Panel	Obstetrics/Gynecology
Regulatory Class	Class II

III. PREDICATE DEVICE INFORMATION

1) Primary predicate device

Trade/proprietary Name	Hi bebe^{super}
Model No.	BT-150S and BT-150L
510(k) Number	K200675

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

IV. DEVICE DESCRIPTION

The Hi bebe^{super} (model: BT-150B) 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.

BT-150B electrical breast 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). BT-150B electrical breast pump also includes back flow protection and it is powered by a 12V DC adaptor or rechargeable lithium battery.

BT-150B electrical breast pump has three operating modes: massage mode, expression mode and program mode to save pressure level and cycle level and their mode (massage or expression) and their running time. Sixteen (16) vacuum pressure levels are available for operating mode ad massage mode. One cycle speed level is available for massage mode and three (3) cycle speed levels are available for expression mode. The device is capable of providing suction up to -270 mmHg.

The subject device is a modified version of BT-150S model of K200675. Compared to the predicate device, the following changes are made.

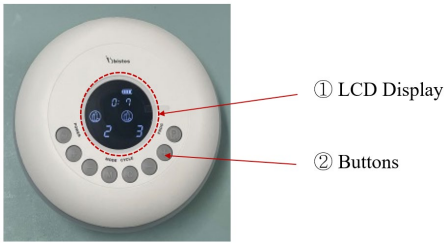
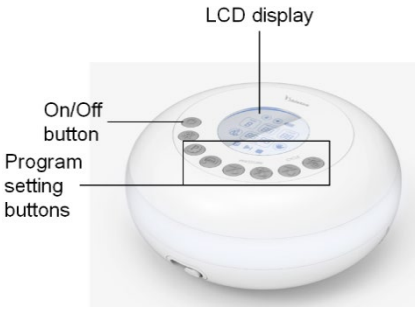
- Power source change. Both AC-powered mode and battery-powered mode are available.
- Vacuum pressure and cycle speed.
- User interface: Compared to the predicate device, the lamp button is removed, increase cycle speed button and decrease cycle speed button are combined as one cycle level change button, and the function of each button is modified.
- Dual motors system: The subject device includes dual pumps while the predicate device includes a single pump. Compared to the predicate device, a sub board has been removed and both pumps are connected to the main board.

V. INDICATIONS FOR USE:

Hi bebe ^{super} (BT-150B) 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 WITH THE PREDICATE DEVICE

The table below compares the intended use and technological characteristics of the subject and predicate device.

Product Name	Hi bebe^{super} K251512	Hi bebe^{super} K200675
Model No:	BT-150B	BT-150S and BT-150L
Manufacturer	Bistos Co., Ltd.	Bistos Co., Ltd.
Indications for use	Hi bebe^{super} (BT-150B) is intended to be used by lactating women for expressing and collecting breast milk. It is intended for a single user.	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.
Use environment	Home, OTC	Home, OTC
Design		
User control	power button program button Mode change button vacuum decrease button vacuum increase button cycle speed button	power button lamp light button program button Mode change button vacuum decrease button vacuum increase button cycle speed increase button cycle speed decrease button
Accessories	1. Funnel (19/21/24/27/32mm) 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 (21/24/27/32 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.
Power	1. AC adaptor: 100-240 Vac, 50/60Hz, 2.0A 2. Battery:	1. Battery: 7.4V Li-ion Polymer 2200mAh Operating time: 120min

Product Name	Hi bebe^{super} K251512	Hi bebe^{super} K200675
	7.4V Li-ion Polymer 1800 mAh Operating time: 210min Charging time: 180min	Charging time: 150min
Maximum vacuum Unit: mmHg	Approx. -290 mmHg	Approx. -290 mmHg
Cycle speed in expression mode	Level 1: 19 to 38 CPM Level 2: 20 to 40 CPM Level 3: 20 to 42 CPM	35/40/45/50/55/60 CPM
Cycle speed in massage mode	68 CPM (Level 1)	70/80/90 CPM
Adjustable Cycle Levels	3 Steps (Expression mode) / 1 Step (Massage mode) of each suction level	3 Steps (Expression mode) / 3 Steps (Massage mode) of each suction level
Vacuum range (mmHg)	Single/Double pumping - Massage mode: 75 - 155mmHg - Expression mode: 70 - 270mmHg	Single pumping - Massage mode: 50 - 230mmHg - Expression mode: 50 - 250mmHg Double pumping - Massage mode: 30 - 150mmHg - Expression mode: 30 - 200mmHg
Adjustable Suction Levels	16 levels	16 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.

In comparison to the predicate device, the subject device has the same intended use - for collection of breast milk from the breasts of lactating women.

As seen in the comparison table, the subject device and the predicate device have different technological features, including the user interface, pump, vacuum range, cycle speed range, power sources, and flange size. These technological differences do not raise different questions

of safety and effectiveness.

VII. SUMMARY OF NON-CLINICAL TESTS

The following data were provided to support the substantial equivalence determination:

Electrical Safety:

Testing was conducted in accordance with ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021], Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005/AMD2:2020) 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/AMD1:2020 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 the 2023 FDA Guidance Document “Content of Premarket Submissions for Device Software Functions.”

Non-clinical Performance Testing

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

- Vacuum pressure and cycle speed testing in each mode
- Operating time/charging Time
- Backflow Protection
- Use 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). All tests met the acceptance criteria.

VIII. CONCLUSIONS

The performance test results described above demonstrate that the Hi bebe^{super}(BT-150B) is as

safe and effective as the predicate device and support a determination of substantial equivalence.