June 29, 2022

Haenim Co., Ltd.
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
1150 Roosevelt, STE 200
Irvine, CA 92620

Re: K211016
Trade/Device Name: Powered Breast Pump (Models 7V and 7X)
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: May 25, 2022
Received: May 31, 2022

Dear Priscilla Chung:

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)*
K211016

Device Name
Powered Breast Pump (Models 7V and 7X)

Indications for Use *(Describe)*

The Powered Breast Pump (Models 7V and 7X) is a single-user, powered breast pump intended to express and collect milk from the breasts of lactating women.

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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"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
K211016

Date: June 28, 2022

1. Applicant / Submitter:

Applicant:	Haenim Co., Ltd.
Address:	15, Saryeom-ro 21beon-gil, Seo-gu, Incheon South Korea, 22742
Contact:	Dae Won Kim
Tel:	+82-32-324-6614

2. Submission Correspondent:

Contact:	Priscilla Chung
Address:	LK Consulting Group USA, Inc. 1150 Roosevelt STE 200, Irvine CA 92620
Phone:	714-202-5789
Fax:	714-409-3357
Email:	juhee.c@lkconsultinggroup.com

3. Subject Device:

Proprietary Name:	Powered Breast Pump (Models 7V and 7X)
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

4. Predicate Device:

Proprietary Name:	Hi bebe^{super} (Models BT-150S and BT-150L)
510(k) Number:	K200675

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

5. Device Description:

The Powered Breast Pump (Models 7V and 7X) is a powered breast pump that is intended to express and collect milk from the breasts of lactating women. The device is intended for a single user and can be used in home and professional healthcare environments.

The subject device can be used for single or double breast pumping and consists of the following key components: a motor unit with a press-button user interface, expression kits (NexusFit™ Cap,

Diaphragm, Pump Body, Breast Shield, and Valve; areola shield; milk collection kit), and a silicone vacuum tube.

The Powered Breast Pump (Models 7V and 7X) has two operational modes (massage and expression), with user-selectable vacuum and cycle levels in each mode (levels are shown in Section 7 of the summary). Both device models are powered by an external AC power supply, while all 7V and select 7X models can be operated using an internal rechargeable lithium-ion battery. The device is provided non-sterile.

All milk contacting components are compliant with 21 CFR 174-179

6. Indications for Use:

The Powered Breast Pump (Models 7V and 7X) is a single-user, powered breast pump intended to express and collect milk from the breasts of lactating women.

7. 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.

	Powered Breast Pump (Models 7V and 7X) K211016	Hi bebe^{super} (Models BT-150S and BT-150L) K200675	Comparison
Manufacturer	Haenim Co., Ltd.	Bistos Co., Ltd.	
Indications for Use	The Powered Breast Pump (7V and 7X) is a single-user, powered breast pump intended to express and collect milk from the breasts of lactating women.	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 subject and predicate device indications for use statements are not identical; however, their intended uses are the same (i.e., for collection of milk from the breasts of lactating women).
Pump Options	Single or Double	Single or Double	Same
Suction Modes	Massage Mode and Expression Mode	Massage Mode and Expression Mode	Same
Pump Type	Diaphragm	Unknown	**Different:** The pump type of the predicate device is not known; however, differences in the pump type do not raise different

				questions of safety and effectiveness.
Visual Indicator	LED-light display		Liquid-crystal display	**Different:** The subject and predicate devices have different display types. Differences in visual indicators do not raise different questions of safety and effectiveness.
User Control	Power Memory Lamp brightness Mode change Decrease vacuum Increase vacuum Decrease speed Increase speed		Power Memory Lamp brightness Mode change Decrease vacuum Increase vacuum Decrease speed Increase speed	Same
Accessories	NexusFit™ Breast Shield Areola shield 21mm Bottle Stand NexusFit™ Cap NexusFit™ Pump Body NexusFit™ Diaphragm NexusFit™ Valve Tubing Nipple Bottle Disk Bottle Cap Bottle Dual Connector Adaptor		Funnel (21/24/27/32 mm) Funnel Block Funnel cap Diaphragm Top, Diaphragm and Diaphragm Bottom Air tube and air tube connector Nipple Bottle Bottle cap Bottle cover and bottle disc	**Different:** The subject device has different packaged components than the predicate device. Differences in device components do not raise different questions of safety and effectiveness.
Power	7V: 1. AC Adaptor input AC100~240V 50/60Hz Adaptor output DC5V 2.0A 2. Battery Li-ion 3.7V 2600mAh	7X: 1.AC Adaptor input AC100~240V 50/60Hz Adaptor output DC12V 2.0A 2. Battery Li-ion 7.4V 2200mAh	Battery power only: 7.4V Li-ion Polymer 2200 mA	**Different**: The subject device operates under both AC and battery power, while the predicate is only battery powered. Differences in power supply do not raise different questions of safety and effectiveness.
Maximum Vacuum Pressure	-290 mmHg		-290 mmHg	Same
Cycle Speed	7V Expression Mode: 30-50 cycle/min	7X Expression Mode: 34-55 cycle/min	Expression Mode: 35/40/45/50/55/60 Cycle/Min. Massage Mode: 70/80/90 Cycle/Min	**Different:** The differences in specifications do not raise different

	Massage Mode: 70-90 cycle/min Expression Mode: 5 levels Massage Mode: 5 levels	Massage Mode: 70-105 cycle/min Expression Mode: 6 levels Massage Mode: 5 levels	Expression Mode: 6 levels Massage Mode: 3 levels	questions of safety and effectiveness.
Vacuum Range (mmHg)	7V Single pumping: Massage mode: -50 to -120 mmHg ± 20% Expression mode: -50 to -250 mmHg ± 20% Double pumping: Massage mode: -30 to -70 mmHg ± 20% Expression mode: -40 to -180 mmHg ± 20% 7X Single pumping: Massage mode: -50 to -140 mmHg ± 20% Expression mode: -50 to -250 mmHg ± 20% Double pumping: Massage mode: -30 to -80 mmHg ± 20% Expression mode: -40 to -190 mmHg ± 20%		Single pumping: Massage mode: -50 to -230 mmHg ± 20% Expression mode: -50 to -250 mmHg ± 20% Double pumping: Massage mode: -30 to -150 mmHg ± 20% Expression mode: -30 to -200 mmHg ± 20%	**Different:** The differences in specifications do not raise different questions of safety and effectiveness.
Adjustable Vacuum Levels	7V 12 levels	7X 15 levels	16 levels	**Different:** The difference in the number of suction levels do not raise different questions of safety and effectiveness.
Backflow 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.	Same
Nursing Night Lamp	Yes		Only applicable to BT-150L	**Different:** Differences in device versions with and without nursing night lamps do not raise different questions of safety and effectiveness.

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.

8. Summary of Non-Clinical Performance Testing

Biocompatibility

Biocompatibility testing was performed in accordance with the 2020 FDA guidance Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process." Testing included the following:

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization (ISO 10993-10:2010)
- Irritation (ISO 10993-10:2010)

The testing supports the biocompatibility of the patient-contacting device materials that were shown to be non-cytotoxic, non-irritating, and non-sensitizing.

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)
- 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.
- IEC 62133-2:2017, Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

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 was evaluated in accordance with the 2005 FDA guidance document Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

Performance Testing

Performance testing was conducted to demonstrate pump performance met established specifications in the following areas:

- Vacuum level verification testing at each mode/cycle demonstrated that the devices meet mode/cycle specifications.
- Backflow protection testing was conducted to verify liquid does not backflow into the tubing.
- Use-life testing was conducted to demonstrate that the device maintains its specifications throughout its proposed use-life.
- Battery performance testing was conducted to demonstrate that the battery remains functional during its stated battery use-life.
- Battery status indicator testing was conducted to demonstrate that the battery status indicator remains functional during its stated battery life.
- Battery charging testing to demonstrate the duration of time needed to fully recharge the battery.

9. Conclusion

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.