March 3, 2023

imani Co.
% Kyung Jin, Lee
Senior Consultant
Global Medical Standard Consulting Co., Ltd.
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Korea

Re: K222573
Trade/Device Name: imani i2Plus Breast Pump
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: February 3, 2023
Received: February 3, 2023

Dear Kyung Jin, Lee:

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,

Monica D. Garcia -S

Monica D. Garcia, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
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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)*
K222573

Device Name
imani i2Plus Breast Pump

Indications for Use *(Describe)*
The imani i2Plus Breast Pump is a powered breast pump to be used by lactating women to express and collect milk from their breast. The imani i2Plus Breast Pump is a single user device.

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 – K222573

1. Submitter Information

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2. Correspondent Information

Contact: Kyung Jin, Lee
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Phone: + 82 (02) 604-96049
Email: kjlee@gmsc.kr

3. Date prepared: February 27, 2023

4. Device Information

Device Name:	imani i2Plus Breast Pump
Common Name:	Powered breast pump
Regulation Number:	21 CFR 884.5160
Regulation Name:	Powered Breast Pump
Product Code:	HGX (Pump, Breast, Powered)
Regulatory Class:	Class II

5. Predicate Device Information

Device Name:	imani i2
510(k) Number:	K202045
Manufacturer:	Imani Co.

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

6. Device Description

The imani i2Plus Breast Pump is an electrically powered wearable single breast pump consisting of the following key components: a funnel, insert, milk collector, valve, protector, connector, charging cable, adaptor, cap, and iBox accessory. It is designed to work in the user's bra and has a rechargeable battery so it can be used hands-free. The main body includes a press-button user interface, pump body, and LCD display. Pumping can be performed on one breast (single pumping) or two breasts (double pumping) when configured with the iBox accessory. The user interface allows the user to switch from massage to pumping mode and control the vacuum levels within those modes. Massage and pumping modes consist of 5 vacuum levels and fixed cycle speeds when used standalone. Massage mode consists of 5 vacuum levels and 1 cycle speed and pumping mode consists of 9 vacuum levels and 3 cycle speeds for each level.

The i2Plus in standalone configuration is capable of providing vacuum levels from 50-150 mmHg at a fixed cycling rate of 65 cycles per minute in massage mode and vacuum levels from 80-270 mmHg with cycling rates from 24-55 cycles per minute in pumping mode. The i2Plus with the iBox accessory is capable of

providing vacuum levels from 150-200 mmHg at a fixed cycling rate of 60 cycles per minute in massage mode and vacuum levels from 150-270 mmHg with cycling rates from 24-55 cycles per minute in pumping mode. The imani i2Plus is charged with a 5 V DC USB type C adaptor and powered by a 3.7 V, 1400mAh internal rechargeable lithium-ion battery. The motor unit operates on embedded software. Software updates by end-users are not supported. The subject device is for repeated use by a single user in a home environment. The device is provided non-sterile.

The breast pump expresses breast milk by creating a seal around the nipple using a flange and applying and releasing suction to the nipple. The milk is collected in a milk collection container, which can be used for storage. To prevent milk from flowing into the vacuum system, a backflow protection membrane physically separates the milk-contacting pathway from the vacuum system.

All other components (i.e., motor unit) of the subject device are not in contact with the breast.

The i2Plus operates on a rechargeable battery when standalone and does not function when charging. When configured with iBox, the pump is only operable when connected with the AC adapter. The rechargeable battery can be charged using the external USB adapter if the motor unit is not in operation.

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

7. Indications for Use

The imani i2Plus Breast Pump is a powered breast pump to be used by lactating women to express and collect milk from their breast. The imani i2Plus Breast Pump is a single user device.

8. 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.

Table 1: Comparator Table for Subject and Predicate Devices

	imani i2Plus breast pump K222573 Subject Device	**imani i2 K202037 Predicate Device**	**Comparison**
Product Name	imani i2Plus Breast Pump	imani i2	**N/A**
Product Code	HGX	HGX	**Same**
Regulation Number	21 CFR 884.5160	21 CFR 884.5160	**Same**
Regulatory Class	Class II	Class II	**Same**
Patient Population	Lactating Women	Lactating Women	**Same**
Indications for Use	The imani i2Plus Breast Pump is a powered breast pump to be used by lactating women to express and collect milk from their breast. The imani i2Plus Breast Pump is a single user device.	The imani i2 breast pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The imani i2 breast pump is a single user device.	**Same Intended Use**
Pump Options	Single or Double	Single	**Similar**
Cycling control mechanism	Microcontroller	Microcontroller	**Same**

Backflow Protection	Yes	Yes	**Same**
Mobile Application	No	No	**Same**
Indicators	Yes, LCD	Yes, LCD	**Same**
Single User	Yes	Yes	**Same**
Media separation (backflow protection)	Yes	Yes	**Same**
Expression pattern	2-Phase	2-Phase	**Same**
Power supply	Li-Ion Battery or mains when connected to iBox	Li-Ion Battery	**Same**
Suction levels (massage)	I2Plus: 50 – 150 mmHg, 5 levels With iBox: 150 – 200 mmHg, 5 levels	50 – 150 mmHg, 5 levels	**Different. Differences in massage suction levels do not raise different questions of safety and effectiveness**
Suction levels (pumping)	I2Plus: 80 – 270 mmHg, 5 levels With iBox: 150 – 270 mmHg, 9 levels	80 – 270 mmHg, 5 levels	**Different. Differences in pumping suction levels do not raise different questions of safety and effectiveness**
Cycles per minute (stimulation)	I2Plus: 65 CPM With iBox: 60 CPM	65 CPM	**Different. Differences in available cycle speed do not raise different questions of safety and effectiveness.**
Cycles per minute (pumping)	I2Plus: 24-55 CPM, 5 levels With iBox: 30-40 CPM, 3 levels available at each suction pressure	24-55 CPM, 5 levels	**Different. Differences in available cycle speed do not raise different questions of safety and effectiveness.**
Suction levels	I2Plus: 5 massage, 5 pumping With iBox: 5 massage, 9 pumping	5 massage, 5 pumping	**Different. Differences in available suction levels do not raise different questions of safety and effectiveness.**
User Interface	On-Off switch, vacuum adjustment, LCD charging status indicator and working hr indicator	On-Off switch, vacuum adjustment, LCD indicator	**Different. Differences in available suction levels do not raise different questions of safety and effectiveness.**
Adjustable Suction Levels	Yes	Yes	**Same**
Design	Milk Collector and Flange	Milk Collector and Flange	**Same**

The indications for use of the subject and predicate device are similar, and they have the same intended use (i.e., for collection of breast milk from the breasts of lactating women).

The subject and predicate devices have similar technological features, including pumping options, control mechanism, user interface, backflow protection, and device indicators. However, as shown in the table above, there are technological differences between the subject and predicate device, including different vacuum and cycle specifications, power supply, wear configurations, and vacuum levels. The different technological characteristics of the subject device, as compared to the predicate device, do not raise different questions of safety and effectiveness.

9. Summary of Non-Clinical Performance Testing

Biocompatibility

Biocompatibility studies, including irritation, cytotoxicity, and sensitization testing were performed in accordance with the 2020 FDA guidance document *Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process",* as follows:

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

The user-contacting materials were shown to be non-cytotoxic, non-irritating, and non-sensitizing.

Electrical Safety
Testing was conducted in accordance with ANSI/AAMI ES60601- 1:2005/A2:2010 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance), 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, 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 was evaluated as recommended in the 2005 FDA guidance document *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*.

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

- 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.

10. Conclusion

The results of the performance testing described above demonstrate that the imani i2Plus Breast Pump is as safe and effective as the predicate device and supports a determination of substantial equivalence.