March 1, 2021

imani Co.
% Do Gyun Lim
Senior Consultant
Global Medical Standard Consulting Co., Ltd.
34, Sangamsan-ro, Mapo-gu
Seoul, 03909
Republic of
KOREA

Re: K202037
Trade/Device Name: imani i2
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: January 27, 2021
Received: January 29, 2021

Dear Do Gyun Lim:

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)*
K202037

Device Name
imani i2

Indications for Use *(Describe)*
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.

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
# K202037

## 1. Submitter's Information


- Name of Manufacturer: imani Co.
- Address: 147, Hwasan-ro, Idong-eup, Cheoin-gu, Yongin-si, Gyeonggi-do, Republic of Korea [Zip.17135]
- Contact Name: Hyo-Soon, Hwang
- Telephone No.: +82-31-323-4435
- Email Address: jea@hello-imani.com


- Date Prepared March 1, 2021

## 2. Device Information

| | |
|---|---|
| **Trade/Device Name** | imani i2 |
| **Common Name** | Powered breast pump |
| **Regulation Number** | 21 CFR 884.5160 |
| **Regulation Name** | Powered breast pump |
| **Regulation Class** | Class II |
| **Product Code** | HGX (Pump, Breast, Powered) |

## 3. Predicate Device Information

- 510(k) Number: K181863
- Trade/Device Name: Elvie Pump

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

## 4. Description of the Device

The imani i2 is a powered breast pump that is intended to express and collect milk from the breasts of lactating women. This breast pump is intended for use by a single user and can be used to pump breast milk from a single breast (single pumping). The imani i2 breast pump is a wearable breast pump comprised of a main body (pump), charging cable, collection bottle, valve, diaphragm for backflow protection, and a breast funnel. It is designed to work in the user's nursing bra and is battery operated so it can be used hands-free without external power cords. The only user-contacting material is polypropylene (breast funnel). The device is provided non-sterile.

The imani i2 breast pump allows the user to adjust the vacuum levels. Two suction patterns, massage and breast pumping mode, are pre-programmed with variable levels and cycle speeds.

The subject device is powered by a rechargeable Li-polymer battery (3.7 VDC, 1400 mAh).

The imani i2 provides the following user features:

- Two displays for level of vacuum and battery.
- Five buttons for power on/off, mode selection (Massage Mode, Pumping Mode), decrease vacuum, and increase vacuum
- Pumping Mode: This mode is used to express and collect milk from the breast. This mode includes five vacuum and cycle speed levels.
- Massage Mode: This mode is used to massage the breast before pumping. This mode includes five vacuum levels and a consistent single cycle speed across all vacuum levels.

## 5. Indications for use

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.

## 6. Comparison of Intended Use and Technological Characteristics

**The table below presents comparisons between the subject device (imani i2) and the legally marketed predicate device (Elvie Pump):**

| | **Subject Device** | **Predicate Device** |
|---|---|---|
| Product Name | imani i2 | Elvie Pump |
| Manufacturer | imani Co. | Chiaro Technology Limited |
| Indications for Use | 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. | The Elvie Pump is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Elvie Pump is intended for a single user. |
| Single user device | Single user | Single user |
| Submission Number | K202037 | K181863 |
| Product Code | HGX | HGX |
| Device Class | II | II |
| Sterility | Not sterile | Not sterile |
| **User Interface and Controls** | | |
| User Controls | LED display for level of pressure and battery, button for on/off, selection mode, increase/decrease vacuum. | Light for bottle and battery level, buttons for on/off, intensity settings, side selector, and play/pause, and mobile app |
| Design | Wearable pump | Wearable pump |
| Pump Options | Single | Single or Double |

| | Subject Device | Predicate Device |
|---|---|---|
| Accessories | • Breast Funnel (sizes: 25 mm and 28 mm [32 mm sold separately])<br>• Collection Bottle<br>• Valve<br>• Diaphragm Backflow Protector<br>• Connector<br>• Charging cable | • Hub<br>• Breast Shield<br>• Bottle<br>• Lid<br>• Seal<br>• Spout<br>• Valve<br>• Charging Cable<br>• Bra Adjuster |
| **Specifications** | | |
| Power sources | Rechargeable battery (Polymer Li-ion, 3.7 V d.c., 1400mAh) | Rechargeable Li-Polymer Battery |
| Suction strength | Pumping mode: 80 – 270 mmHg, 5 levels<br>Massage mode: 50 – 150 mmHg, 5 levels | 40-220 mmHg, 7 levels |
| Cycle speed | Pumping mode: 24 – 55 CPM<br>Massage mode: 65 CPM | 66 – 120 CPM |
| Backflow Protection | Yes | Yes |

The indications for use statement of the subject device is identical to the predicate device. Therefore, the subject and predicate devices have the same intended use.

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

## 5. Non-Clinical Test summary

The following data were provided in support of the substantial equivalence determination:

1) Electrical Safety/Electromagnetic Compatibility Testing in accordance with the following standards:

- AAMI / ANSO ES 60601-1 /A1:2012, Medical Electrical Equipment: Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2:2014, Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests
- 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 [Including: Technical Corrigendum 1 (2011)]. (General II (ES/EMC))
- IEC 62133:2012, 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

2) Software Validation

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 a moderate level of concern.

3) Biocompatibility

Biocompatibility testing was conducted in accordance with the 2020 FDA guidance “Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing.” Testing included the following assessments:

- Cytotoxicity per ISO 10993-5:2009
- Sensitization per ISO 10993-10:2010
- Irritation per ISO 10993-10:2010

The user-contacting materials were shown to be biocompatible.

4) Bench Performance Testing

Bench performance testing was conducted to demonstrate device performance, including vacuum level settings, cycle speed settings, and backflow/cross-contamination protection. Device specifications were met for all tests conducted.

In addition, the following testing was conducted on the battery:

- Battery use-life testing
- Battery charging time
- Battery indicator/operating time

5) Simulated Use Testing

After reading the User Manual, the subjects completed the usability tasks and then completed a post-test satisfaction questionnaire. Results of testing demonstrated that users can properly use the device.

## 8. Conclusion

The subject and predicate device have the same intended use and the technological differences do not raise different questions of safety or effectiveness. The performance data demonstrate that the subject device is as safe and effective as the predicate device and support the determination of substantial equivalence.