February 26, 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: K202045
Trade/Device Name: imani i1
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)*
K202045

Device Name
imani i1

Indications for Use *(Describe)*
The imani i1 is a powered breast pump to be used by lactating women to express and collect milk from their breasts. This device is intended for multiple users.

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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510(k) Summary
K202045

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 February 26, 2021

2. Device Information

Trade/Device Name	imani i1
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: K190810
- Trade/Device Name: OPERA, OPERA Eco

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

4. Description of the Device

The imani i1 breast pump is a powered breast pump that is intended to express and collect milk from the breasts of lactating women. The pump component of this device can be used by multiple users using separate collection accessories. The user has the option to pump breast milk from a single breast (single pumping) or from both breasts (double pumping). The imani i1 breast pump is comprised of a main pump body, diaphragm and cap for backflow protection, valve, milk bottle connector, a breast shield, breastmilk storage packset (30pcs), and air hose hub. The only user-contacting material is polypropylene (breast shield). The device is provided non-sterile.

The imani i1 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 speed (pump speed). The subject device is AC-powered (AC adaptor: 100 – 240 V, 50/60 Hz, 550 mA [Output: 12VDC, 2A]).

The imani i1 breast pump provides the following user features:

- Three displays for level of cycle, time, and vacuum
- Eight buttons for power on/off, mode selection, decrease vacuum and cycle, increase vacuum and cycle, and light control
- Breast Pumping Mode: This mode is used to express and collect milk from breast. This mode includes 12 vacuum levels and 6 cycle speed levels.
- Massage Mode: This mode is used to massage the breast before pumping. This mode includes 6 vacuum levels and 2 cycle speed levels.

5. Indications for use

The imani i1 is a powered breast pump to be used by lactating women to express and collect milk from their breasts. This device is intended for multiple users.

6. Comparison of Intended Use and Technological Characteristics

The table below presents comparisons between the subject device (imani i1) and the legally marketed predicate device (OPERA, OPERA Eco):

	Subject Device (K202045)	**Predicate Device (K190810)**
Product Name	imani i1	OPERA, OPERA Eco
Manufacturer	imani Co.	Unimom Co.
Indications for Use	The imani i1 is a powered breast pump to be used by lactating women to express and collect milk from their breasts. This device is intended for multiple users.	The OPERA & OPERA eco are multiple-user, powered breast pumps intended to express and collect milk from the breasts of lactating women.
Single user device	Multiple users	Multiple users
Submission Number	K202045	K190810
Product Code	HGX	HGX
Device Class	II	II
Sterility	Not sterile	Not sterile
User Interface and Controls		
User Controls	Display, button for on/off, mode selection, increase/decrease vacuum and cycle, and light control	Switch control - Power, Vacuum / Cycle Up or Down - Mode switch LCD Display
Pump Options	Single or double	Single or double
Accessories	• Breast shield (size 24 mm, 28 mm [sold separately]) • Protector (diaphragm and cover cap) • Valve • Milk bottle connector • Adaptor (Output: 12 V d.c., 2A) • Breastmilk Storage PackSet • Air Hose Hub	• Air tube • Breast shield kit with back-flow protector • Bottle • Bottle cover • Nipple • Bottle cap • Bottle disk • Bottle stand • Adapter

	Subject Device (K202045)	Predicate Device (K190810)
		• Air tube connector • Silicone massager
Specifications		
Power sources	AC/DC wall adapter (12 V d.c., 2A)	AC/DC Adapter (14 V DC, 2A) Rechargeable lithium polymer battery (Opera)
Pump type	Diaphragm	Diaphragm
Suction strength	30 – 270 mmHg	45-280 mmHg
Cycles per minute (massage mode)	70-80 cycles/min (adjustable), 2 levels	60-100 cycles/min
Suction levels (massage mode)	6	5
Cycles per minute (expression mode)	30-55 cycles/min (adjustable), 6 levels	26-42 cycles/min
Suction levels (pumping mode)	12	8
Backflow Protection	Yes	Yes

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

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

7. Non-Clinical Test Summary

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

1) Electrical Safety/Electromagnetic Compatibility

Testing in accordance with the following standards:

- AAMI / ANSI 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))

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.

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.