October 10, 2018

Chiaro Technology Limited
% Marc C. Sanchez, Esq.
Regulatory Attorney
Contract In-House Counsel and Consultants, LLC
53516 Bickett
Chapel Hill, NC 27517

Re: K181863
Trade/Device Name: Elvie Pump
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered breast pump
Regulatory Class: II
Product Code: HGX
Dated: July 11, 2018
Received: July 12, 2018

Dear Marc C. Sanchez:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael T. Bailey -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181863

Device Name
Elvie Pump

Indications for Use *(Describe)*
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.

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."

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510(K) Summary – K181863

The following information is provided as required by 21 CFR 807.87 for the Elvie Pump 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the information upon which the substantial equivalence is based.

Sponsor: Chiaro Technology Limited
63-66 Hatton Garden
London EC1N 8LE United Kingdom
Establishment Registration: 3012098706

Manufacturer: Jabil Circuit (Shanghai) LTD.
600 Tian Lin Road, Shanghain, China 200233
Establishment Registration: 3005210579

Contact: Marc C. Sanchez, Esq.
Contract In-House Counsel and Consultants, LLC
53516 Bickett Chapel Hill NC 27517
Ph: 202.765.4491
E-mail: msanchez@fdaatty.com

Date Prepared: October 9, 2018

Proprietary Name: Elvie Pump

Common Name: Powered breast pump

Regulation Number: 21 CFR 884.5160, Powered breast pump

Regulatory Class: Class II

Product Code: HGX (pump, breast, powered)

Predicate Device(s): Medela Freestyle (K150499)

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

Device Description:

The Elvie Pump is an electric breast pump system comprised of a single or double portable unit that integrates the pump body and milk collection bottle. It consists of a pump (motor unit) and includes a breast shield, bottle, seal, valve, spout and bra adjustor. All components (minus the pump) are reusable and may be manually cleaned. The kit components may be purchased separately and are available in different sizes and configurations.

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The Elvie Pump includes piezoelectric pump technology which generates negative pressure on the nipple to express milk, which is collected in the integrated milk collection bottle. It is designed to work in the user's nursing bra and has a rechargeable battery so it can be used hands-free without external power cords or milk collection tubes.

The Elvie Pump is a battery-powered electro-mechanical device that contains software. It can be controlled through the physical interface on the device or through a mobile companion app, which also provides real-time milk monitoring, pump battery life, pumping time elapsed and pumping history information.

All milk contacting components are constructed out of food grade materials that are compliant with 21 CFR 174-179.

Indications for Use:

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.

The subject and predicate device have the same intended use.

Comparison of Technological Characteristics:

The Elvie Pump uses the same fundamental technology and mode of action as the predicate device, the Medela Freestyle powered electric breast pump (K150499). The table below summarizes the key specifications of the Elvie Pump and the predicate.

Attribute	Predicate Device Medela Freestyle	Subject Device Elvie Pump
510(k) number	K150499	K181863
Product code	HGX	HGX
Classification Name	Pump, Breast, Powered	Pump, Breast, Powered
Indications for Use	The Freestyle is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Freestyle is intended for a single user.	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.
Intended Use	Express milk from breast	Express milk from breast

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Traditional 510k Submission
Elvie Pump

Single User Device	Yes	Yes
Single / Double Pumping	Both	Both
Patient Population	Lactating women	Lactating women
Environment of Use	Home	Home
Over the Counter (OTC)	Yes	Yes
Power Source	AC adaptor or Rechargeable Li-Ion Battery	Rechargeable Li-Polymer Battery
Adjustable Suction Levels	Yes	Yes
Backflow Protection	Yes	Yes
Suction Level (mmHg)	40-245	40-220
Cycles per Second	1.7-1.93	1.1-2.0
Cycles per Second	0.83-1.36	0.6-1.0
Two-phase Expression	Yes	Yes
User Interface	Pump body	Pump body and/or mobile app
Software	Yes	Yes
Control Mechanism	Microcontroller	Microcontroller
Portable	Yes	Yes
Milk Quantity Measurement	No	Yes

As evidenced by the table above, there are differences in technological characteristics between the subject and predicate device. These differences in technological characteristics do not raise different questions of safety or effectiveness.

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Summary of Non-Clinical Test Reports:

The following performance tests were conducted on the Elvie Pump device:

- Biocompatibility testing demonstrating that the patient contacting device components are biocompatibility, including the following specific tests:
    - Cytotoxicity per ISO 10993-5
    - Irritation per ISO 10993-10
    - Sensitization per ISO 10993-10
- Software validation for a minor level of concern per the FDA guidance document "Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005, including cybersecurity assessment and validation of the milk measurement algorithm
- Simulated use testing (usability study) per IEC 62366-1 Application of Usability Engineering to Medical Devices
- Use life testing to support the proposed use life
- Electrical safety testing per IEC 60601-1 and IEC 60601-1-11
- Electromagnetic compatibility testing per and IEC 60601-1-2
- Cleaning validation on the reprocessing instructions included in the labeling
- Device performance testing including evaluation of vacuum performance and backflow demonstrating that the subject device meets its specifications

Conclusion:

The Elvie Pump is substantially equivalent to the predicate device.