August 25, 2021

Chiaro Technology Limited
℅ Marc C. Sanchez, Esq.
Regulatory Attorney
Contract In-House Counsel and Consultants, LLC
d/b/a FDA Atty
53516 Bickett
Chapel Hill, NC 27517

Re: K210936
Trade/Device Name: Elvie Stride
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: July 21, 2021
Received: July 28, 2021

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/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, 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)*
K210936

Device Name
Elvie Stride

Indications for Use *(Describe)*
The Elvie Stride is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Elvie Stride 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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510(K) Summary

K210936

Submitter Information:

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

Manufacturer: Sanmina-SCI Systems De Mexico SA De CV
Km 15.5 No. 29, Plant 06
Carr. Chapala-Guadalajara Jalisco, MX 45640
Establishment Registration: 3006544299

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 510(k) Summary Prepared: August 23, 2021

Device Information:

Device/Trade Name:	Elvie Stride
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
Review Panel:	Obstetrics/Gynecology

Predicate Device:

510(k) Number:	K181863
Manufacturer:	Chiaro Technology Limited
Device Name:	Elvie Pump

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

Device Description:

Elvie Stride is an electric breast pump that is intended for lactating women to express and collect breast milk. It is intended for a single user. It may be operated as a single or double pumping system.

Elvie Stride has adopted the in-bra aesthetic. It is designed to work in the user's nursing bra and has a rechargeable battery so it can be used hands-free without any external power cords. The pump is located off the body and the milk collection bottle is located on the breast. It expresses milk by applying negative pressure to the nipple so that expressed milk may collect in the milk collection bottle. It can be controlled through the physical interface on the pump or through a mobile companion app.

Elvie Stride consists of 15 components: Hub, Breast Shield, Cup Front, Diaphragm Seal, Valve, Stopper, Tubing, Tube Splitter, Hub Connector, Cover, Cup Seal, Cap, Cap Seal, Clip and USB Charging Cable. All components are reusable and may be manually cleaned or placed on the top shelf of a dish washer.

Indications for Use:

The Elvie Stride is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Elvie Stride is intended for a single user.

Comparison of Intended Use and Technological Characteristics:

The following table compares the subject device to the predicate device with respect to the indications for use and technological characteristics:

Attribute	*Subject Device* *Elvie Stride* *K210936*	*Predicate Device* *Elvie Pump* K181863	Comparison
Indications for Use	The Elvie Stride is a powered breast pump to be used by lactating women to express and collect milk from their breasts. The Elvie Stride 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.	Identical
Intended Use	Express milk from breast	Express milk from breast	Identical
Single User Device	Yes	Yes	Identical
Single / Double Pumping	Both	Both	Identical
Patient Population	Lactating women	Lactating women	Identical
Environment of Use	Home	Home	Identical
Over the Counter	Yes	Yes	Identical
Power Source	USB cable (battery charger) and Li-Ion Battery	USB cable (battery charger) and Li-Polymer Battery	Different
Adjustable Suction Levels	Yes	Yes	Identical
Backflow Protection	Yes	Yes	Identical
Suction Strength	35-260 mmHg (double) 55-300 mmHg (single)	40-220 mmHg	Different
Maximum Suction Strength	300 mmHg	220 mmHg	Different
Cycle Speed	31 to 83 cycles/min (Stimulation) 18 to 51 cycles/min (Expression)	1.1 to 2.0 cycles per/sec (Stimulation) 0.6 to 1.0 cycles/sec (Expression)	Different
Expression levels	10	7	Different
Pump Type	Rotary Electric Pump	Piezoelectric Pump	Different
Two-phase Expression	Yes	Yes	Identical

User Controls	On pump body and/or through app	On pump body and/or through app	Identical
Control Mechanism	Microcontroller	Microcontroller	Identical
Mobile App	Yes	Yes	Identical
Milk Quantity Measurement	No	Yes	Different

The subject and predicate device have the same intended use – to express and collect milk from lactating women. The subject and predicate device have different technological features, including the power source, suction strength, pump type, and milk quantity measurement. These technological differences do not raise different questions of safety or effectiveness.

Summary of Non-Clinical Testing:
Non-clinical tests were conducted to verify that the proposed device met all design specifications and that the subject devices are substantially equivalent to the predicate device.

a. Biocompatibility
Biocompatibility testing in accordance with the FDA guidance "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" dated September 4, 2020. Testing included the following assessments:
- Cytotoxicity per ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- Sensitization per ISO 10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
- Irritation per ISO 10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

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

b. Electrical Safety, Electromagnetic Compatibility, and Wireless Technology
- IEC 60601-1:2005+CORR.1:2006+CORR.2:2007+A1:2012, Medical electrical equipment – Part 1: General requirements for basic safety, and essential performance with US deviations per AAMI/ANSI ES 60601-1:2005/(R)2012 and A1:2012.
- 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 60601-1-2:2014, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Compatibility
- 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
- Documentation provided in accordance with the FDA Guidance document, "Radio Frequency Wireless Technology in Medical Devices" dated August 14, 2013.

c. Software Verification
Software verification and validation in accordance with the FDA Guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" dated May 11, 2005.

d. Performance Testing
- Vacuum pressure and cycle rate testing was conducted at all settings and demonstrated that the device met its specifications.
- Backflow testing was conducted to demonstrate that liquid does not backflow into the tubing/pump.
- 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.

Conclusion:

The comparison and analysis above demonstrate that the Elvie Stride is as safe and effective as the predicate device and supports a determination of substantial equivalence to the predicate device.