September 26, 2024

Chiaro Technology Ltd
Amelia Ortiz Rios
Regulatory Affairs Manager
63-66 Hatton Garden
London, EC1N 8LE
UNITED KINGDOM

Re: K242125
Trade/Device Name: Elvie Stride 2
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Dated: July 19, 2024
Received: August 29, 2024

Dear Amelia Ortiz Rios:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,
Gynecology, and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
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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)*
K242125

Device Name
Elvie Stride 2

Indications for Use *(Describe)*
Elvie Stride 2 is a powered breast pump to be used by lactating women to express and collect milk from their breasts. Elvie Stride 2 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 – K242125

1. Submitter Information

Applicant: Chiaro Technology Ltd
Address: 63-66 Hatton Garden
EC1N 8LE, London
UK

2. Correspondent Information

Contact: Amelia Ortiz Rios
Regulatory Affairs Manager,
Email: Amelia.ortiz@chiaro.co.uk
Phone: +44 7 470 359 206

3. Date prepared: September 26, 2024

4. Device Information

Device Name:	Elvie Stride 2
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:	Elvie Stride
510(k) Number:	K210936
Manufacturer:	Chiaro Technology Ltd

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

6. Device Description

The Elvie Stride 2 is an electrically powered breast pump to be used in a home environment by a single user. The device is provided non-sterile and can be used on one breast (single pumping) or on both breasts at the same time (double pumping).

The subject devices are capable of expression and stimulation modes with ten associated suction levels for each. The subject device features on/off buttons, level up/down buttons, mode selection buttons, suction level/time LED indicators/battery visual indicator display/mode displays. The pumps are powered by internal, non-replaceable, rechargeable lithium-ion batteries which are charged using the included cable. The subject device cannot be operated while plugged into AC power.

The breast pumps use cyclic negative pressure (suction) to mimic the suckling patterns of a feeding infant. A DC motor drives a membrane vacuum pump to generate the suction required to stimulate and express breast milk. The timing of this pattern is dependent upon the suction/speed settings selected by the user and is pre-programmed in the devices. Elvie Stride 2 includes the Elvie Stride hub, including the existing firmware and mobile application functionality.

The device is capable of producing peak suction levels between -35 and -260 mmHg when double pumping, -55 and -300 mmHg when single pumping, and operating at speeds between 52 to 103 cycles per minute for stimulation mode and 28 to 76 cycles per minute for expression mode. There are two available pumping modes with 10 distinct levels of vacuum and cycle speed. The subject device ensures backflow protection between the breast shield and the electronic components via a physical barrier (diaphragm) mechanism.

The subject device includes a 28mm breast shield and 5 separate silicone insert sizes (24, 21, 19, 17 and 15 mm). The breast shield may be used with or without the addition of a nipple insert. The cup assembly includes components which are in contact with breastmilk. All food contacting components are composed of food grade material and have been tested to 21 CFR 174-177.

7. Indications for Use

Elvie Stride 2 is a powered breast pump to be used by lactating women to express and collect milk from their breasts. Elvie Stride 2 is intended for a single user.

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

	Elvie Stride 2 K242125 Subject Device	**Elvie Stride K210936 Predicate Device**	**Comparison**
Product Code	HGX	HGX	Same
Regulation Number Device Class	21 CFR 884.5160 Class II	21 CFR 884.5160 Class II	Same
Single User	Yes	Yes	Same
Wear Configuration	Mobile/portable for use in bra	Mobile/portable for use in bra	Same
Single/Double Breast Pump	Yes	Yes	Same
Single/double pump	Single or Double	Single or Double	Different
Media Separation (Backflow Protection)	Yes	Yes	Same
Sterility	Non-sterile	Non-sterile	Same
Direct User Contact	Yes, breast shield and inserts	Yes, breast shield	Equivalent
Cycling Control Mechanism	Microcontroller	Microcontroller	Same
Accessories	Nipple Inserts in 5 sizes: 24mm, 21mm, 19mm, 17mm, 15 mm	None	Different
Power Supply	Rechargeable Lithium-Ion battery	Rechargeable Lithium-Ion battery	Same
Suction Strength (stimulation) (Expression)	Single:-55 to -300 mmHg Double:-35 to -260 mmHg	Single:-55 to -300 mmHg Double:-35 to -260 mmHg	Same

Cycle speed (cycles/min): (Stimulation)	52 to 103 cycles/min	31 to 83 cycles/min	Equivalent
Cycle speed (cycles/min): (Expression)	28 to 76 cycles/min	18 to 51 cycles/min	Equivalent
Suction Levels (stimulation)/(expression)	10	10	Same
Visual Indicator	LED display	LED display	Same
User Interface	5-Buttons on Pump Body: on/off, mode select, play/pause, increase vacuum, decrease vacuum	5-Buttons on Pump Body: on/off, mode select, play/pause, increase vacuum, decrease vacuum	Same
Mobile Application	Yes	Yes	Same
Overall design	Tabletop	Tabletop	Same
Environment of Use	Home	Home	Same

The indications for use of the subject and predicate device are identical and they have the same intended use – the expression and collection of breast milk.

The subject and predicate devices have similar technological features, including available number of available vacuum levels, single/double pumping operation, and cycle speed specifications. However, as shown in the table above, there are some technological differences between the subject and predicate device, including differences in cup assembly and inclusion of nipple inserts. However, the different technological characteristics of the subject device do not raise different questions of safety and effectiveness.

9. Summary of Non-Clinical Performance Testing

Biocompatibility

Biocompatibility information was provided in accordance with Attachment G, Biocompatibility of Certain Devices in Contact with Intact Skin, of the 2023 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."*

Electrical Safety

Testing was leveraged from the predicate device and was conducted in accordance with IEC 60601- 1 Edition 3.2 2020-08 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 Edition 3.1 2020-07 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 leveraged from the predicate device and was conducted in accordance with IEC 60601-1-2:2014+A1: 2020 Medical Electrical Equipment - Part 1-2: "*General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests."*

Software

Software was leveraged from the predicate device and was evaluated at the equivalent of Basic Documentation level as recommended in the 2023 FDA guidance document "*Content of Premarket Submissions for Device Software Functions."*

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 leveraged from the predicate to demonstrate that the battery remains functional during its stated battery use-life.
- Battery status indicator testing was leveraged from the predicate 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 Elvie Stride 2 is as safe and effective as the predicate device and supports a determination of substantial equivalence.