



June 11, 2026

AViTA Corporation
Rex Hsieh
Regulatory Affairs Specialist
9F, No.78, Sec.1, Kwang-Fu Road, Sanchong Dist.,
New Taipei City, 24158
TAIWAN

Re: K250129
Trade/Device Name: AViTA Breast Pump
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered Breast Pump
Regulatory Class: II
Product Code: HGX
Received: October 29, 2025

Dear Rex Hsieh:

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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (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, PhD
Assistant Director
DHT3B: Division of Reproductive,
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Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K250129

Device Name
AViTA Breast Pump

Indications for Use (Describe)

The AViTA Breast Pump is intended to express and collect milk from the breasts of lactating women, and to alleviate engorgement of the breast. The device 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.

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510(k) Summary - K250129

1. Submitter Information

Name: AViTA Corporation
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Dist., New Taipei City 24158, Taiwan (R.O.C.)
Phone: +886-2-8512-1568 ext.5306
Correspondent: Rex Hsieh (rex_hsieh@avita.com.tw)

2. Date of Summary: June 10, 2026

3. Device Information

Trade Name: AViTA Breast Pump
Common Name Powered Breast Pump
Regulation Number: 21 CFR 884.5160
Regulation Name: Powered breast pump
Product Code: HGX (Pump, Breast, Powered)
Classification Panel Obstetrics/Gynecology
Device Class: Class II

4. Predicate Device Information

510(k) Number: K201381
Predicate Trade Name: Philips Avent single/double electric breast pump
Advanced

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

5. Device Description

The AViTA Breast Pump is an electric breast pump intended to express milk and collect milk from the breasts of lactating women, and to alleviate engorgement of the breast. It is provided non-sterile and is a reusable device intended for a single user in home and professional healthcare environments.

The device includes a single model, the AViTA BR10, and consists of two key components: a motor unit with a touch screen user interface and expression kit with milk collection container. The motor unit is connected to the expression kit via a silicone tube. The motor unit can be connected to two expression kits simultaneously.

It is an electrically powered, software-controlled, digital breast pump. It is powered by a rechargeable lithium-ion battery (3.7 V, 2900mAh) that can be charged using an external charger. The device is designed not to be used during charging. The device operates with embedded software and does not incorporate any off-the-shelf (OTS) software.

The device includes two (2) operating modes – Simulation mode and Expression mode, and each mode has five (5) suction levels. The user interface of the device consists of four buttons and an LED display. The buttons include power button (used to turn on/off the device and play/pause the pumping program), mode selection button to choose between the two modes and the level increase and decrease buttons to select one of five levels. The device LED display shows the current mode, level, countdown timer, and battery level.

The device extracts milk from the breasts by creating a seal around the nipple and applying and releasing suction to the nipple. The milk is collected in a milk collection container, which can be used for storage. To prevent milk from flowing into the vacuum system, the expression kit includes a silicone diaphragm that physically separates the milk-contacting pathway from the vacuum system. All milk contacting components of the device are compliant with 21 CFR 177.

6. Indications for Use / Intended Use

The AViTA Breast Pump is intended to express and collect milk from the breasts of lactating women, and to alleviate engorgement of the breast. The device is intended for a single user.

7. Comparison of Intended Use and Technological Characteristics of the Subject Device and Predicate Device

The table below compares the intended use and technological characteristics of the subject and predicate device.

Item	Subject Device AViTA Breast Pump (K250129)	Predicate Device Philips Avent single/double electric breast pump Advanced (K201381)	Comparison
Classification	Pump, Breast, Powered	Pump, Breast, Powered	Same
Regulation	Class II, 21 CFR 884.5160	Class II, 21 CFR 884.5160	Same
Product code	HGX	HGX	Same
Intended use	The AViTA Breast Pump is intended to express and collect milk from the breasts of lactating women, and to alleviate engorgement of the breast. The device is intended for a single user.	The Philips Avent single/double electric breast pump Advanced is intended to express and collect milk from the breast of a lactating woman, and to alleviate engorgement of the breast. The device is intended for a single user.	Same
User population	Lactating woman	Lactating woman	Same
Single user	Yes	Yes	Same
Pump options	Single or double pumping	Single or double pumping	Same
Media separation (Backflow protection)	Yes (Silicone diaphragm on the expression kit, which separates the vacuum system of the motor unit from milk-contacting parts)	Yes (Silicone diaphragm on the expression kit, which separates the vacuum system of the motor unit from milk-contacting parts)	Same
Cycling control mechanism	Microcontroller	Microcontroller	Same
Suction modes	Stimulation Mode Expression Mode	Stimulation Mode Expression Mode	Same
Adjustable suction levels	Yes	Yes	Same
Vacuum range	Stimulation mode:	Stimulation mode:	Different

Item	Subject Device AViTA Breast Pump (K250129)	Predicate Device Philips Avent single/double electric breast pump Advanced (K201381)	Comparison
	-45 to -190 mmHg (5 Levels) Expression mode: -145 to -270 mmHg (5 Levels)	-45 to -150 mmHg Expression mode: -45 to -270 mmHg	
Cycle speed	Stimulation mode: 75 to 150 cycles/min (5 Levels) Expression mode: 38 to 60 cycles/min (5 Levels)	Stimulation mode: 105 to 120 cycles/min Expression mode: 53 to 85 cycles/min	Different.
Controls (User interface)	4 Buttons (On-Off-Pause-Play, Stimulation or Expression mode, Decrease vacuum level, Increase vacuum level)	4 Buttons (On-Off-Pause-Resume, Stimulation or Expression mode, Decrease vacuum level, Increase vacuum level)	Same
Indicators	LED indicators: Level/mode indicator, Timer, Battery level indicator	LED indicators: Level/mode indicator, Timer, Battery level indicator	Same
Power connection	USB Type-C (power only)	Micro-USB (power only)	Different.
Power supply	Lithium-ion battery (3.7 V 2900 mAh)	AC-Adapter (100-240 V primary and 5 V secondary) or Lithium-ion battery (3.6V 2600mAh) for battery-operated devices	Different

The indications for use of the subject and predicate devices are similar, and both devices have the same intended use (i.e., for the collection of breast milk from the breasts of lactating women).

The subject and predicate devices have similar technological features, including pumping options, pumping options, backflow protection and same maximum suction pressure (270mmHg). While there are differences in technological characteristics between the subject and predicate devices, including vacuum pressure, cycle frequency, battery, and charger, these differences do not raise different questions of safety and effectiveness.

8. Summary of Non-Clinical Performance Testing

The following performance tests were conducted on the AViTA Breast Pump to support a substantial equivalence determination:

➤ **Biocompatibility Testing**

The biocompatibility evaluation for the patient contacting components of the subject device was conducted in accordance with the 2023 FDA Biocompatibility Guidance *Use of International Standard ISO10993-1, “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process”*) as follows:

- ISO 10993-5:2009, Biological evaluation of medical devices–Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2021, Biological evaluation of medical devices–Part 10: Tests for skin sensitization
- ISO 10993-23:2021, *Biological evaluation of medical devices–Part 23: Tests for skin irritation*

➤ **Electrical Safety and EMC Testing**

The electrical safety, and electromagnetic compatibility testing was conducted per the following standards:

- IEC 60601-1-2 :2014/AMD:2020 *Medical electrical equipment–Part 1-2: General requirements for basic safety and essential performance–Collateral standard: electromagnetic compatibility*
- IEC TR 60601-4-2 :2016 *Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems*
- IEC 60601-1 :2005/AMD2:2020 *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance* with US national differences,
- IEC 60601-1-11 :2005/AMD2:2020 *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 62133-2:2017/AMD1:2021 – *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*

➤ **Software Verification and Validation Testing**

Software verification and validation were conducted in compliance with 2023 FDA Guidance “*Content of Premarket Submissions for Device Software Functions*”.

➤ **Non-Clinical Performance Testing**

A series of performance tests were conducted on the subject device to demonstrate that the device meets its design requirements and performs as intended. The performance tests include:

- Vacuum pressure and cycle frequency testing at all modes and levels
- Battery operating and charging time testing
- Button life test of breast pump
- Backflow protection testing
- Use life testing

These tests were conducted in single and double pumping mode, and the device met the pre-defined acceptance criteria.

9. Conclusion

The results of the performance testing described above demonstrate that AViTA Breast Pump is as safe and effective as the predicate device and supports a determination of substantial equivalence.