October 30, 2026

My123Baby Medical Limited Dba Boost Fertility
% Carmen Brown
Regulatory Consultant
Proxima CRO
2450 Holocombe Blvd.
Houston, Texas 77021

Re: K262066
Trade/Device Name: Pleiades Device
Regulation Number: 21 CFR 884.6160
Regulation Name: Assisted Reproduction Labware
Regulatory Class: Class II
Product Code: MQK
Dated: June 18, 2026
Received: June 22, 2026

Dear Carmen Brown:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K262066

Device Name
Pleiades Device

Indications for Use *(Describe)*
The Pleiades Device is intended for preparing motile sperm from semen for use in treatment of infertile couples by intracytoplasmic sperm injection (ICSI), in vitro fertilization (IVF), and intrauterine insemination (IUI) procedures.

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
K262066

1. Submitter Information:

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2. Submission Correspondent:

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3. Date of Summary: October 28, 2026

4. Device Identification:

Device Trade Name:	Pleiades Device
Common Name:	Sperm Separation Device
Regulation Name:	Assisted Reproduction Labware
Regulation Number:	21 CFR 884.6160
Device Class:	Class II
Product Code:	MQK (Labware, Assisted Reproduction)

5. Predicate Device:

Device Trade Name:	LensHooke CA1 Sperm Separation Device, LensHooke CA0 Sperm Separation Device
510(k) Number:	K221810

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

6. Device Description:

The Pleiades Device is a sterile, single-use sperm purification device for use by healthcare professionals to provide washed sperm samples to be used for assisted reproduction techniques, such as intracytoplasmic sperm injection (ICSI), in vitro fertilization (IVF), and intrauterine insemination (IUI) procedures.

The Pleiades Device is comprised of two chambers with a channel layer between them that are used to separate sperm. The bottom, or “inlet,” chamber receives the native semen sample through a female luer lock valve, and the sperm then swim up through the channel layer. The channel layer creates an environment with boundaries for the sperm to swim along, separating motile sperm from less motile sperm, debris and seminal plasma in a sample. Once complete, the purified sperm sample will be at the top, or “outlet,” chamber of the device for collection by the user.

7. Indications for Use:

The Pleiades Device is intended for preparing motile sperm from semen for use in treatment of infertile couples by intracytoplasmic sperm injection (ICSI), in vitro fertilization (IVF), and intrauterine insemination (IUI) procedures.

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: Intended Use and Technological Characteristics Comparison

Characteristic/Feature	Subject Device K262066	Predicate Device K221810
Device Name	Pleiades Device	LensHooke CA1 Sperm Separation Device, LensHooke CA0 Sperm Separation Device

Regulation Number Product Code Device Class	884.6160 MQK Class II	884.6160 MQK Class II
Design	A disposable device containing a base, a star-shaped channel layer, and 2 ports on the device: one for native sample and buffer loading and one for sperm collection after processing.	A disposable device containing a base, filter layer(s), and a port on the filter for media loading and sperm collection after processing. -CA0 with one filer layer -CA1 with two filter layers
Mechanism of Action	Liquefied semen and buffer are added to the device. The star-shaped channels that achieve sperm purification are manufactured and assembled within the device; no user assembly is required. The loaded device is incubated at 37°C for a total of 40 minutes to allow motile sperm to swim up through the channel layer and into the outlet chamber.	Liquefied semen is added to the base. The filter(s) are placed on the base and separation medium added through the layer port. The loaded device is incubated at 37℃ for 30 minutes to allow motile sperm to swim up and across the filter(s) to migrate into the separation medium in the upper filter layer.
Materials	Polycarbonate, silicone, polypropylene copolymer, stainless steel, and acrylic copolymer	Polycarbonate
Sterility	EO (SAL 10^-6)	Radiation sterilized (SAL 10^-6)
HSSA	≥80% of the control motility at 24 h after exposure for 30 min	⩾80% of the control motility at 24 h after exposure for 30 min
Endotoxin (LAL)	<20 EU/device	<20 EU/device
Shelf-life	One year (12-months)	Two years (24-months)

The subject device and predicate device have the same indications for use and intended use. The subject device has similar mechanism of actions and design as the predicate device, relying on sperm motility to separate motile sperm from non-motile sperm or non-sperm cells in a closed container. The devices differ in materials, sterility (e.g., method), and shelf-life. These differences in technology do not raise different questions of safety and effectiveness and can be evaluated through performance testing.

9. Summary of Non-Clinical Performance Testing:

The following tests were conducted on the subject device to support a determination of substantial equivalence to the predicate device:

- Sterilization validation study per SO 11135:2014, *Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2018)]*
- Package integrity and transportational testing after accelerated aging to the end of the 12-month shelf-life duration. Testing included the following:
    - Environmental conditioning per ASTM D4332-22, *Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing*
    - Simulated shipping distribution per ASTM D4169-22, DC-13, *Standard Specification for Performance Testing of Shipping Containers and Systems*
    - Package integrity testing consisting of:
        - Visual inspection per ASTM F1886/F1886M-16
        - Seal strength per ASTM F88/F88M-23
        - Dye penetration per F1929-23
- Endotoxin testing per USP <85>: <20 EU/device
- Human Sperm Survival Assay (HSSA) before and after accelerated aging to support a 12-month shelf-life: ≥80% of the control motility at 24 hr after exposure for 30 minutes
- Performance testing:

  The subject device was used to separate motile sperm cells from native semen samples. The separation procedures followed the Instructions for Use, and the percentage of motile sperm cells in the harvested output samples were compared to the input samples. The subject device was tested in parallel with the predicate devices. The sperm separation results were comparable to the predicate device. A summary of the results for the subject device are provided in Table 2 below:

Table 2: Sperm Separation Results

Device name	% motile sperm (before/after separation)	% change in total motility	% progressive motile sperm (PMSC) (before/after	% change in PMSCs

			separation	
Pleiades Device	49.4%/83.0%	33.6%	40.2%/78.7%	38.5%

10. Conclusion:

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