October 26, 2026

Contrario Medical, Inc.
% Allison Komiyama
Consultant
DuVal & Associates
825 Nicollet Mall
Suite 1820
Minneapolis, Minnesota 55402

Re: K262276
Trade/Device Name: Cyperus
Regulation Number: 21 CFR 884.6160
Regulation Name: Assisted Reproduction Labware
Regulatory Class: II
Product Code: MQK
Dated: September 23, 2026
Received: September 25, 2026

Dear Allison Komiyama:

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.

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,

REBECCA DORSEY -S

For
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K262276

Device Name
Cyperus

Indications for Use *(Describe)*
Cyperus is intended for preparing motile sperm from semen for use in the 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
K262276

1. Submitter Information

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3. Date of Summary

October 26, 2026

4. Device Identification

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

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

Cyperus is used by lab personnel of reproductive health clinics to process human semen samples. The device helps to separate and allow collection of motile sperm for assisted reproductive technology (ART) procedures. The sterile single-use device leverages natural behavior of sperm to swim.

The Cyperus device is intended for preparing motile sperm from semen for use in the treatment of infertile couples by intracytoplasmic sperm injection (ICSI), in vitro fertilization (IVF) and intrauterine insemination (IUI) procedures. The Cyperus device dimensions are 39.2mm x 77.2mm x 13.6mm and when empty, weighs 14 grams. There is a lower chamber with an inlet port where the semen sample is injected into, and an upper chamber where the sperm buffer is added and where the final optimized sperm sample is removed after incubation.

7. Indications for Use

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

8. Comparison of 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	Predicate
510(k) Number	K262276	K221810
Device Name	Cyperus	LensHooke CA1 Sperm Separation Device, LensHooke CA0 Sperm Separation Device
Sponsor Name	Contrario Medical Inc.	Bonraybio Co., Ltd.
Regulation Number Product Code Device Class	884.6160 MQK Class II	884.6160 MQK Class II
Design	A disposable device containing a base, two filter layers, a port for semen loading, an upper chamber with removable lid for media loading and sperm collection after processing. The top filter is for sperm separation, while the bottom one is used for the collection of excess fluid.	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
Indications for Use	Cyperus is intended for preparing motile sperm from semen for use in the treatment of infertile couples by intracytoplasmic sperm injection (ICSI), in vitro fertilization (IVF) and intrauterine insemination (IUI) procedures.	The LensHooke CA0 Sperm Separation Device and the LensHooke CA1 Sperm Separation Device are intended for preparing motile sperm from semen for use in the treatment of infertile couples by intracytoplasmic sperm injection (ICSI), in vitro

		fertilization (IVF) and intrauterine insemination (IUI) procedures.
Mechanism of Action	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.	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, cellulose acetate, and polymethylmethacrylate	Polycarbonate
Sterility	Radiation sterilized (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	Three months	Two years (24-months)

The subject device has a similar mechanism of action 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. However, the predicate device has several filter options (e.g., one or two filters). The devices differ in materials 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 ISO 11137-1:2006/(R) 2015, *Sterilization of health care products - Radiation - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*
- Package integrity and transportational testing after accelerated aging to the end of the three 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
        - Bubble leak testing per F2096-11
- Endotoxin testing per USP <85>: <20 EU/device

- Human Sperm Survival Assay (HSSA) before and after accelerated aging to support a three month shelf-life: ≥80% of the control motility at 24 h after exposure for 30 min
- Performance testing:

  The subject device was used to separate motile sperm cells from raw 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. A summary of the results is provided in Table 2 below:

Table 2: Summary of Results

Device name	% motile sperm (before/after separation)	% change in total motility	% progressive motile sperm (PMSC) (before/after separation	% change in PMSCs
Cyperus	65.47%/100.0%	34.53%	58.73%/97.33%	38.6%

9. Conclusions

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