October 31, 2022

Bonraybio Co., LTD.
℅ Feng-Yu Lee
Principal Regulatory Consultant
IVDD Regulatory Consultant
29122 Rancho Viejo Road, Suite 212
San Juan Capistrano, CA 92675

Re: K221810
Trade/Device Name: LensHooke CA0 Sperm Separation Device
LensHooke CA1 Sperm Separation Device
Regulation Number: 21 CFR§ 884.6160
Regulation Name: Assisted reproduction labware
Regulatory Class: II
Product Code: MQK
Dated: September 28, 2022
Received: September 29, 2022

Dear Feng-Yu Lee:

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 801and Part 809); 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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221810

Device Name
LensHooke CA0 Sperm Separation Device
LensHooke CA1 Sperm Separation Device

Indications for Use *(Describe)*
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.

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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bonraybio

510(K) Summary
K221810

1 Submitter/Correspondent:

1.1 Submitter:

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1.2 Submission Correspondent:

IVDD Regulatory Consultant
29122 Rancho Viejo Road, Suite 212, San Juan Capistrano, CA 92675
Contact Person: Feng-Yu Lee
TEL: 1-949-218-0929
FAX: 1-949-218-0928

1.3 Date Summary Prepared: October 27, 2022

2 Subject Device:

Proprietary Name:	LensHooke CA0 Sperm Separation Device LensHooke CA1 Sperm Separation Device
Common Name:	Sperm Separation Device
Regulation Name:	Assisted Reproduction Labware
Regulation Number:	884.6160
Product Code:	MQK
Regulatory Class:	II

3 Predicate Device:

ZyMōt Multi Sperm Separation Device (850µl, 3 mL)
Device Company: DxNow, Inc.
510(k) Number: K173075

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

4 Device Description

The LensHooke CA0 Sperm Separation Device and LensHooke CA1 Sperm Separation Device are used to prepare motile sperm from semen based on the mobility of motile sperm.

The LensHooke Sperm Separation Device has a base and filter layers to separate and process

the semen sample. The LensHooke Sperm Separation Device has two models, CA0 with one filter layer and CA1 with two filter layers. Liquefied semen (1 mL) is added to the base and sperm washing medium is added to the filter via a filter port. After incubation, the separated sperm are collected from the filter layer via the filter port.

The subject devices are radiation-sterilized with a sterility assurance level (SAL) of 10^{-6}. The LensHooke Sperm Separation Devices are individually packaged and for single-use only.

5 Indications for Use

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.

6 Comparison of Intended Use and Technological Characteristics with the Predicate Device:

Product Name	LensHooke® CA0 and CA1 Sperm Separation Device (Subject Device)	ZyMōt Multi Sperm Separation Device (850 µL, 3 mL) (Predicate Device - K173075)
Indications for Use	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.	The ZyMōt Multi Sperm Separation 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.
Design	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	ZyMōt Multi – A disposable culture dish containing a separation chamber and an inlet port. The separation chamber has a lower sample chamber and an upper collection chamber. The two chambers are separated by a microporous filter.
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.	ZyMōt Multi – The semen is added to the inlet port to fill the lower sample chamber; then, the separation medium is added to the upper collection chamber. The loaded device is incubated at 37℃ for 30 minutes to allow motile sperm to swim up and cross the filter to migrate into the over-laying separation medium in the upper collection chamber.

Material	Polycarbonate	Polymethylmethacrylate, polycarbonate, flash-spun high-density polyethylene fibers
Human Sperm Survival Testing	≥80% of the control motility at 24 hours after exposure for 30 minutes	≥80% of the control motility at 24 hours after exposure for 30 minutes
Endotoxin	≤20 EU/device	≤2.5 EU/device
Sterile	Yes	Yes
Shelf-Life	24 months	12 months

The subject and predicate devices have the same indications for use and intended use. The subject device and predicate device have the same fundamental design incorporating a chamber for loading semen, a filter for motile sperm to migrate through, and a port for collection of motile sperm. However, there are technological differences between the subject and predicate devices, including the number of filters, materials, endotoxin specifications, and shelf-life duration). These differences do not raise different questions of safety and effectiveness.

7 Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence is as follows：

The following testing has been performed on the LensHooke CA0 and CA1 Sperm Separation Devices:

- Sterilization Validation Study per ISO 11137-1:2006
- Transportation Simulation Study per ISTA 3A (2018)
- Package integrity testing following accelerated aging per ASTM F1980-21 to support a 2-year shelf-life:
  - Dye penetration testing per ASTM F1929-15
  - Seal strength testing Per ASTM F88/F88M-15
- Endotoxin testing per USP<85> and ANSI/AAMI ST72:2019: <20 EU/device
- Human Sperm Survival Assay (HSSA) before and after accelerated aging to support a 2-year shelf life:
  - Donor sperm were exposed to the subject devices for 30 minutes and then, incubated at room temperature for 24 hours. The rate of motile sperm after incubation was compared to that of the control (no exposure to the subject device). The acceptance criterion is ≥80% of the control motility at 24 hours after exposure for 30 minutes
- Sperm Separation Performance:
  - Each version of the subject device was used to separate motile sperm from donor semen samples. The separation procedures followed the Instructions for Use, and the percentage of motile sperm and progressively motile sperm in the output samples were compared to those of the input samples. The results showed an average improvement in total motility of 24.4% and 25.9% for the CA0 and CA1 devices, respectively. The results showed an average improvement in progressive motility of 26.6% and 27.1% for the CA0 and CA1 devices, respectively.

8 Conclusions

The subject and predicate devices have the same intended use and comparable technological characteristics. The differences in technological characteristics between the subject and predicate devices do not raise different questions of safety and effectiveness. The performance data demonstrate that the subject devices are substantially equivalent to the predicate device.