February 20, 2025

iPreg Incorporation
Ching-Wen Chang
R&D Head
4F-3., No. 77, Sec. 1, Xintai 5th Rd., Xizhi Dist.
New Taipei City, 221
TAIWAN

Re: K241626
Trade/Device Name: SperSort™ Sperm Sorting Chip (IPG02)
Regulation Number: 21 CFR 884.6160
Regulation Name: Assisted Reproduction Labware
Regulatory Class: II
Product Code: MQK
Received: January 24, 2025

Dear Ching-Wen Chang:

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,

Michael T. Bailey -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K241626

Device Name
SperSort™ Sperm Sorting Chip (IPG02)

Indications for Use *(Describe)*
The SperSort™ Sperm Sorting Chip 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.

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510(k) SUMMARY
K241626

Submitter/Address	iPreg Incorporation 4F-3., No. 77, Sec. 1, Xintai 5th Rd., Xizhi Dist., New Taipei City, 221, Taiwan (R.O.C.) Telephone: +886-8771-3721
Contact Person:	Ching-Wen Chang iPreg Incorporation 4F-3., No. 77, Sec. 1, Xintai 5th Rd., Xizhi Dist., New Taipei City, 221, Taiwan (R.O.C.) Telephone: +886-8771 -3721 Email: cwchang@ipreginc.com
Date Prepared:	February 20, 2025
Trade Name:	SperŜort™ Sperm Sorting Chip (IPG02)
Common Name:	Sperm Separation Device
Regulation Name:	Assisted Reproduction Labware
Regulation Number:	21 CFR 884.6160
Regulatory Class:	Class II
Product Code:	MQK (Labware, Assisted Reproduction)
Predicate Device:	ZyMot Multi Sperm Separation Device (K173075)
	The predicate device has not been subject to a design-related recall.

Device Description:

The SperŜort™ Sperm Sorting Chip is used to prepare motile sperm for assisted reproductive technology (ART) procedures. The device separates motile sperm from the semen based on the mobility (i.e., swim-up nature) of motile sperm.

The SperŜort™ Sperm Sorting Chip consists of an upper collection chamber and a lower semen sample chamber. The chambers are separated by porous filter which allow motile sperm to pass from the lower chamber to the upper chamber. Both the semen sample injection port and sperm collection port are located on the upper cover. The semen sample injection port directly connects to the lower chamber, while the sperm collection port is connected to the upper chamber.

The SperŜort™ Sperm Sorting Chip accommodates a 1.9 mL semen sample. Liquefied semen is added to the lower chamber and cleared sperm washing medium (1.5 mL) is added to the upper chamber. Following incubation for 30 minutes at 37ºC, the isolated sperm are gathered from the collection port.

The SperŜort™ Sperm Sorting Chip is a radiation-sterilized device with a sterility assurance level (SAL) of 10^{-6}. They are individually packaged and for single use only.

Indication for Use:

The SperŜort™ Sperm Sorting Chip 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.

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

The table below includes a comparison of the intended use and technological characteristics of the subject and predicate devices.

	Subject Device SperŜort™ Sperm Sorting Chip K241626	**Predicate Device ZyMot Multi Sperm Separation Device K173075**	**Comparison**
Indications for Use	The SperŜort™ Sperm Sorting Chip 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	The ZyMōt Multi 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	Same

	intrauterine insemination (IUI) procedures.	intrauterine insemination (IUI) procedures.	
Design	The SperŜort™ Sperm Sorting Chip has a processing volume of 1.9 mL. The device consists of upper and lower case separated by a porous membrane. The semen injection port on the cover connects to the lower semen chamber, while the sperm washing buffer loading and sample collection port connects to the upper chamber.	The ZyMōt Multi Sperm Separation Device has two processing volumes, 850µl and 3ml. Each version has 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.	**Different:** The subject and predicate devices have differences is designs. These differences in design do not raise different questions of safety and effectiveness (S&E).
Mechanism of action	Liquefied semen is placed in the lower chamber via the semen injection port and cleared sperm washing medium is placed in the upper chamber via the sperm washing buffer loading and sample collection port. The loaded device is incubated at 37°C 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.	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 37ºC 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.	**Same**
Material	Polycarbonate	Polymethylmethacrylate, polycarbonate, flash-spun high-density polyethylene fibers.	**Different:** The subject device is comprised of different materials than the predicate device. This difference in materials does not raise different questions of S&E.
Sterilization	Gamma Irradiation Sterilization (SAL 10^{-6})	Gamma Irradiation Sterilization (SAL 10^{-6})	Same
Usage	Single-use only	Single-use only	Same
Shelf-Life	2-Years	12-Months	**Different:** The subject device has a longer shelf-life than the predicate device. This difference in shelf-life does not raise different questions of S&E.
Prescription Use	Yes	Yes	Same
Endotoxin	≤ 20 EU/device	≤ 2.15 EU/device	**Different:** The subject device has a higher limit for endotoxin than the predicate

			device. This difference in endotoxin limit does not raise different questions of S&E.
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	Same

As shown in the table above, 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 device materials, device volumes, and device specifications. These differences do not raise different questions of safety and effectiveness.

Non-Clinical Performance Data

The following studies have been performed to support substantial equivalence to the predicate device:

Sterilization Testing:

Radiation sterilization and validation was conducted in accordance with ISO 11137-1:2018, 11137-2:2015, and the 2024 FDA Guidance Document, *Submission and Review of Sterility Information in Premarket Notification (510(k) Submissions for Devices Labeled as Sterile*. The subject devices have a Sterility Assurance Level (SAL) of 10^{-6}.

Simulated Transportation/Package Integrity:

Simulated transportation and package integrity testing was performed after accelerated aging to the end of the stated two-year shelf-life per ASTM F1980-21. The simulated transportation and package integrity assessments conducted are shown below:

- Simulated transportation conditioning per ASTM D4169-22
- Visual inspection of packaging per ASTM F1886/F1886M-16
- Dye penetration testing per ASTM F1929-23
- Seal strength (peel) testing per ASTM F88/F88M-23

The testing above demonstrated that devices can withstand the rigors of shipping and maintain the sterile barrier over the stated shelf-life duration.

Shelf Life:

The following tests were completed and demonstrated that the subject devices maintained their performance in newly manufactured devices and after two years of

accelerated aging per ASTM F1980-21:

- Human sperm survival (HSSA) testing: ≥ 80% of the control motility at 24 hours after exposure for 30 minutes

Endotoxin Testing:

Testing conducted in accordance with USP<85>: <20 EU/device.

Performance Testing:

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 total motile sperm and progressively motile sperm in the output samples were compared to those of the input samples. A summary of the results is provided in the table below:

	% motile sperm (before/after separation)	% change in total motility	% progressive motile sperm cells (PMSC) (before/after separation)	% change in PMSC
SperŜort™ Sperm Sorting Chip	57.50 / 95.89%	38.39%	47.07 / 92.97%	45.90%

Conclusion:

The results of the performance testing described above demonstrate that the SperŜort™ Sperm Sorting Chip is as safe and effective as the predicate device and supports the determination of substantial equivalence.