



March 14, 2024

CytoSwim Ltd.  
% Zennia Paniwnyk  
Senior Regulatory and Quality Consultant  
Insight Regulatory Consultancy Ltd.  
Unit A, Wixford Park, Georges Elm Lane,  
Alcester, Warwickshire B50 4JS  
United Kingdom

Re: K232980  
Trade/Device Name: SpermAlign Sperm Separation Device  
Regulation Number: 21 CFR§ 884.6160  
Regulation Name: Assisted Reproduction Labware  
Regulatory Class: II  
Product Code: MQK  
Dated: February 20, 2024  
Received: February 20, 2024

Dear Zennia Paniwnyk:

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.

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](mailto: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

OHT3: Office of GastroRenal, ObGyn,  
General Hospital and Urology Devices

Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K232980

Device Name  
SpermAlign Sperm Separation Device

### Indications for Use (Describe)

The SpermAlign Sperm Separation Device is intended for preparing motile sperm from semen for use in the treatment of infertile couples by intracytoplasmic sperm injection (ICSI) and in vitro fertilization (IVF) 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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## 510(k) Summary K232980

### 1. Submitter

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**Date Prepared:** March 11, 2024

### 2. Correspondent Information

**Contact Person:** Zennia Paniwnyk  
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### 3. Device Information

**Proprietary Name:** SpermAlign Sperm Separation Device  
**Common Name:** Sperm Separation Device  
**Regulation Name:** Assisted reproduction labware  
**Regulation Number** 21 CFR 884.6160  
**Regulatory Class:** II  
**Product Code:** MQK (Labware, assisted reproduction)

### 4. Predicate Device

Predicate Device	510(k) Number
ZyMot ICSI Sperm Separation Device, ZyMot Multi Sperm Separation Device (850µl, 3ml)	K173075

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

**5. Description of Device**

SpermAlign is a sperm separation device used to prepare motile sperm for assisted reproductive technology (ART) procedures. Separation is achieved through a fluid filled microstructure which guides the motile sperm to the central collection outlet isolating it from the remaining sample. The device utilizes a total processing volume of 180ul of liquefied semen added in 30ul aliquots to each of the six outer wells and sperm washing media added to the central well. Following incubation for 30 minutes, the concentrated motile sperm is withdrawn from the central well and may be used directly in intracytoplasmic sperm injection (ICSI) or in vitro fertilization (IVF) procedures.

SpermAlign is sterilized using X-Ray irradiation and has a sterility assurance level (SAL) of  $10^{-6}$ . The devices are individually packaged and for single use only.

**6. Indications for Use**

The SpermAlign Sperm Separation Device is intended for preparing motile sperm from semen for use in the treatment of infertile couples by intracytoplasmic sperm injection (ICSI) and in vitro fertilization (IVF) procedures.

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

The following table compares the intended use and key technological characteristics of the subject and predicate device:

<b>Characteristic / Feature</b>	<b>SpermAlign Sperm Separation Device (subject device) – K232980</b>	<b>ZyMot Multi Sperm Separation Device (850µl, 3ml) (predicate device) – K173075</b>
Indication for use	The SpermAlign Sperm Separation Device is intended for preparing motile sperm from semen for use in the treatment of infertile couples by intracytoplasmic sperm injection (ICSI) and in vitro fertilization (IVF) 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	SpermAlign is a disposable, circular device. The lid has 6 identical outer wells and a central well. A microstructure covers the inside surface of the base to direct the motile sperm to the central outlet.	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	Media is added via the central well to cover the microstructure. Liquefied semen is added to each of the 6 inlet ports and media further added to the central well. The device is incubated for 30 minutes allowing the motile sperm to swim against the microstructure pillars to the central well for collection.	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°C for 30 min 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	Polypropylene and silicone adhesive	Polymethylmethacrylate, polycarbonate, flash-spun high-density
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	≤2.15 EU/device
Sterile	Radiation sterilized	Radiation sterilized
Shelf-Life	12 months	12 months

The subject and predicate devices have similar indications for use and same intended use. The subject device and predicate device have similar mechanisms of action, incorporating a chamber for loading semen, structure enabling 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 differences in the design, materials and endotoxin specifications. These differences do not raise different questions of safety and effectiveness as compared to the predicate device.

**8. Summary of Non-Clinical Performance Testing**

The following testing has been performed on the SpermAlign Sperm Separation Device:

- Sterilization Validation per ISO 11137-1:2006(R)2015 [Including: Amendment 1 (2013) and Amendment 2 (2018)] & ISO 11137-2:2013/Amd 1:2022, to meet Sterility Assurance Level of 10<sup>-6</sup>.
- Transportation Simulation per ASTM D4169-22
- Package integrity testing following accelerated aging per ASTM F1980-21 to support a 12-month shelf-life:
  - Visual inspection (ASTM F1886/F1886M)
  - Bubble leak (ASTM F2096-11 (2019))
  - Seal strength (ASTM F88/F88M-16)
- 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 12-month shelf life:

Donor sperm were exposed to the subject device 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 30 minutes exposure to SpermAlign.

- Sperm Separation Performance:

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 (see table below for a summary of the results).

Device	Average percent of progressively motile sperm (before/after separation)
SpermAlign	57.4%/91.9%

**9. Conclusion**

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