January 31, 2025

MotilityCount ApS
Jacob Møllenbach
Co-Founder
Gl. Køge Landevej 57, 2.
Valby, DK-2500
DENMARK

Re: K241348
Trade/Device Name: SwimCount® Harvester (1 mL); SwimCount® Harvester (3 mL)
Regulation Number: 21 CFR 884.6160
Regulation Name: Assisted Reproduction Labware
Regulatory Class: II
Product Code: MQK
Dated: January 3, 2025
Received: January 3, 2025

Dear Jacob Møllenbach:

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241348

Device Name

SwimCount® Harvester (1 mL);
SwimCount® Harvester (3 mL)

Indications for Use *(Describe)*

The SwimCount® Harvester is intended for preparing motile sperm cells 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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510(k) Summary

SwimCount® Harvester

1. Submitter

MotilityCount ApS
Gl. Køge Landevej 57, 2.
DK-2500 Valby
Denmark

2. Contact

Jacob Møllenbach
Co-Founder, MotilityCount ApS
Email: jm@motilitycount.com
Telephone Number: +4521445919

3. Summary Preparation Date: January 30, 2025

4. Device Identification

Trade Name:	SwimCount® Harvester (1 mL); SwimCount® Harvester (3 mL)
Common Name:	Sperm Separation Device
Regulation Name:	Assisted Reproduction Labware
Regulation Number:	24 CFR 884.6160
Product Code:	MQK (Labware, Assisted Reproduction)
Regulatory Class:	Class II

5. Predicate Device

ZyMōt Multi (K173075). The predicate device has not been subject to a design-related recall.

6. Device Description

The SwimCount® Harvester (1 mL and 3 mL) is a sperm separation device used to prepare sperm samples for Assisted Reproductive Technology (ART) procedures. The SwimCount® Harvester separates the sperm sample by allowing motile sperm cells to pass the SwimCount® Harvester's membrane system. The SwimCount® Harvester has a design/technology that utilizes the motility of the sperm cells (i.e. swim-up nature) to separate the motile sperm cells from the rest of the

sperm population.

The SwimCount® Harvester has two processing volumes, 1 mL and 3 mL. The device consists of 3 compartments: 1) Sample compartment (1 mL or 3 mL), 2) Medium/Harvest compartment (0.8 mL for both device versions), and 3) Microporous polycarbonate (PC) filter membrane (10 μm pore size).

Each device version has a Semen Inlet port that communicates with the lower sample compartment. The sample compartment is separated from the upper collection compartment by the microporous filter membrane. Semen is added to the lower compartment through the sample inlet port and cleared sperm separation medium (not provided) is added to the upper collection compartment through the Medium Inlet port. After incubation, the separated motile sperm cells are collected from the upper collection compartment through the Harvest Outlet port and used for subsequent assisted reproduction fertilization procedures.

The SwimCount® Harvester is supplied to the user as sterile (radiation), with a sterility assurance level of (SAL) of 10^{-6}. The devices are individually packed and for single use only.

7. Indications for use

The SwimCount® Harvester is intended for preparing motile sperm cells 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 Intended Use and Technological Characteristics with the Predicate Device

Comparison of Intended Use and Technological Characteristics are outlined in Table 1.

Table 1. Comparison between Subject Device (SwimCount® Harvester) and Predicate Device (ZyMōt Multi)

Device name	**SwimCount® Harvester (Subject Device)**	ZyMōt Multi **(Predicate Device)**	**Rationale for Substantial Equivalence**
510(k) number	K241348	K173075	N/A
Company	MotilityCount ApS	DxNow, Inc.	N/A
Classification	II	II	Same
Product code	MQK	MQK	Same
Prescription/ Over-the-Counter	Prescription	Prescription	Same

Indication for use	The SwimCount® Harvester is intended for preparing motile sperm cells 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).	Same intended use
Design	Uses micropore technology (a polycarbonate (PC) filter membrane) to allow motile sperm cells to migrate from the raw sample placed in the lower compartment into sperm separation medium in the collection compartment.	Uses micropore technology (a polycarbonate (PC) filter membrane) to allow motile sperm cells to migrate from the raw sample placed in the lower sample chamber into sperm separation medium in the collection chamber.	Same
Mechanism of action	The semen is added to the inlet port to fill the lower sample chamber; then, the separation medium is added to the upper collection compartment through the medium inlet port. The loaded device is incubated at 37°C for 30 min to allow motile sperm cells to swim up and cross the filter membrane to migrate into the over-laying separation medium in the upper collection compartment. The motile sperm cells are then aspirated with a syringe through the outlet port.	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°C for 30 min to allow motile sperm cells to swim up and cross the filter membrane to migrate into the over-laying separation medium in the upper collection chamber. The motile sperm cells are then aspirated with a syringe through the outlet port.	Same
Semen Volume	1 mL and 3 mL	0.85 mL and 3 mL	Similar
Materials	Filter membrane: polycarbonate Housing: TOPAS (cyclo-olefin copolymer)	Filter membrane: polycarbonate Housing: Flash-spun high-density polyethylene fibers polymethylmethacrylate	Differences in device materials do not raise different questions of safety and effectiveness.
Human Sperm Survival Assay (HSSA)	≥80% of control motility at 24h	≥80% of the control motility at 24 hours after exposure for 30 minutes	The differences between the subject and predicate device HSSA specifications do not raise different questions of safety and effectiveness.

Endotoxin	<20 EU/Device	<2.15 EU/Device	The differences between the subject and predicate device endotoxin specifications do not raise different questions of safety and effectiveness.
Sterile	Yes (radiation)	Yes (radiation)	Same

The subject and predicate devices have comparable indications for use and the same 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.

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 11137-2:2015
- Package integrity and transportation testing after accelerated aging to the end of the 24-month shelf-life duration. Testing included the following:
    - Transportation simulation study per /ASTM D4169-22, DC13
    - Package integrity testing on aged devices and following transportation simulation per ASTM D4169-22:
        - Visual inspection per ASTM F1886/F1886M-16
        - Dye penetration testing per ASTM F1929-15
        - Seal strength testing per ASTM F88/F88M-21
- Endotoxin testing per USP<85>: <20 EU/device
- Human Sperm Survival Assay (HSSA) before and after accelerated aging to support a 24-month shelf-life: ≥80% of control motility at 24h
- Performance testing:

  Each version of the subject device (1 mL and 3 mL) was used to separate motile sperm cells from raw semen samples. The separation procedures followed the Instructions for Use, and the % motile sperm cells in the harvested output samples were compared to those of the input samples. A summary of the results is provided in Table 2 below:

  Table 2: Performance testing of subject device variants (1 mL and 3 mL) n=10:

Device variant	% motile sperm (before/after separation)	% change in total motilty	% progressive motile sperm cells (PMSC) (before/after separation)	% change in PMSCs
SwimCount® Harvester 1 mL	65.4% / 95.1%	45.4%	56.8% / 89.6%	57.8%

SwimCount® Harvester 3 mL	64.4% / 94.9%	47.4%	54.2% / 89.6%	65.3%

10. Conclusion

The results of the performance testing described above demonstrate that SwimCount® Harvester (1 mL and 3 mL) are as safe and effective as the predicate device and supports a determination of substantial equivalence