June 27, 2019

MotilityCount ApS
Jacob Mollenbach
Co-Founder
G1. Koge Landevej 55
Valby, DK-2500 Dk

Re: K183602
Trade/Device Name: SwimCount Sperm Quality Test
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: POV
Dated: January 2, 2019
Received: January 4, 2019

Dear Jacob Mollenbach:

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 801 and 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Takeesha Taylor-Bell
Branch Chief
Hematology Devices
Division of Immunology and Hematology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183602

Device Name
SwimCount™ Sperm Quality Test

Indications for Use *(Describe)*

The SwimCount™ Sperm Quality Test is a qualitative test that detects sperm concentration above or below 5,000,000 Progressive Motile Sperm Cells per mL (PMSCs/mL). The test is intended for use as an aid in the determination of a man's fertility status. For in vitro, over-the-counter use.

The number of progressively motile sperm cells is only one factor that contributes to a male's fertility status. The SwimCount™ Sperm Quality Test does not provide a complete evaluation of a male's fertility status. For a comprehensive assessment of male fertility status then the patient should consult a physician.

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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Section 5 - 510(k) Summary

Summary - SwimCount™ Sperm Quality Test – Summary

Version: 8

Date: 30th April 2019

510(k) Summary

Submitter:	MotilityCount ApS
Address:	Gl. Køge Landevej 55 DK-2500 Valby, Denmark
Contact:	Jacob Møllenbach Co-Founder
Telephone Number:	45-21445919
Email:	jm@motilitycount.com

Summary Preparation Date:	30th April 2019
Device Description:	The SwimCount™ Sperm Quality Test is intended for home use and is a pre-screening sperm quality test that measures the number of Progressive Motile Sperm Cells per mL (PMSCs/mL) .
Trade Name:	SwimCount™ Sperm Quality Test
Common Name:	Semen Analysis Device
Classification Name:	Automated Differential Cell Counter
Regulatory Class:	Class II
Product Code:	POV
C.F.R. Section:	21 CFR 864.5220

Predicate Device

	Manufacturer	Brand Name	510(k) Number
Primary	Genosis Ltd	Fertell Male Fertility Test	K041039

Device Description

The SwimCount™ Sperm Quality Test is intended for *in vitro*, over-the-counter, use and is a pre-screening sperm quality test that measures the number of Progressive Motile Sperm Cells per mL (PMSCs/mL) .

The SwimCount™ Sperm Quality Test is a qualitative test that detects sperm concentration above or below 5,000,000 Progressive Motile Sperm Cells per mL (PMSCs/mL).

The SwimCount™ Sperm Quality Test cut-off value is derived from the WHO laboratory manual for the Examination and processing of human semen, 5th edition guidelines 2010.

The SwimCount™ Sperm Quality Test Kit includes the following components:

- SwimCount™ Sperm Quality Test Box
- SwimCount™ Sperm Quality Test Device
- Semen Collection Cup (used to collect the sperm sample and the sample is to remain in the sample cup for 30 minutes)
- Semen Transfer Pipette (syringe) (used to stir the semen sample 10 times before adding the sample to the Device and further used to collect 0.5 mL semen sample from the sperm sample placed in the cup)
- SwimCount™ Sperm Quality Test Instructions for Use

Indications for use

The SwimCount™ Sperm Quality Test is a qualitative test that detects sperm concentration above or below 5,000,000 Progressive Motile Sperm Cells per mL (PMSCs/mL). The test is intended for use as an aid in the determination of a man's fertility status. For *in vitro*, over-the-counter use.

The number of progressively motile sperm cells is only one factor that contributes to a male's fertility status. The SwimCount™ Sperm Quality Test does not provide a complete evaluation of a male's fertility status. For a comprehensive assessment of male fertility status the patient should consult a physician.

Technological Similarities and Differences to the Predicate

Similarities		
Item	**Device - SwimCount™ Sperm Quality Test**	**Predicate - Fertell Male Fertility Test**
Indications for Use	The SwimCount™ Sperm Quality Test is a qualitative test that detects sperm concentration above or below 5,000,000 Progressive Motile Sperm Cells per mL (PMSCs/mL).	The Fertell Male Fertility Test intended use is to measure motile sperm in semen as an adjunctive screen of male fertility.
Intended Use	The SwimCount™ Sperm Quality Test is intended for use as an aid in the determination of a man's fertility status. For *in vitro*, over-the -counter use	Same
Test Type	Qualitative	Same
Sample Type	Human Semen	Same
Test Setting	For *in vitro*, over-the-counter use	Same
Technology	The PMSCs are separated from the rest of the semen sample, stained and captured on a detection filter. The more PMSCs the darker the test result.	Sperm migration

Differences		
Item	**Device – SwimCount™ Sperm Quality Test**	**Predicate – Fertell Male Fertility Test**
Assay principle	The test result is read as a color intensity and compared to two reference colors. The darker the color the higher the number of PMSCs/mL.	Visual line; colored label bound to sperm.
Primary cut-off Level	5 M PMSCs/mL (derived from WHO 5th edition guidelines 2010)	10 M/mL motile sperm cells (lower reference limit, WHO 4th edition guidelines 1999)
Test Temperature	Ambient	98.6° F ~ 37° Celsius
Result Reading	The test result is read as a color intensity and compared to two reference colors. The darker the color the higher the number of PMSCs/mL.	Visual line; colored label bound to sperm
Primary cut-off Level	5 M PMSCs/mL (derived from WHO 5th edition guidelines 2010)	10 M/mL motile sperm cells (lower reference limit, WHO 4th edition guidelines 1999)

1. Discussion of Technological Similarities between the SwimCount™ Sperm Quality Test and the Primary Predicate Device: Fertell Male Fertility Test

The SwimCount™ Sperm Quality Test and the Primary Predicate Device have the same indication for use, intended use, sample type and test setting.

2. Discussion of Technological Differences between SwimCount™ Sperm Quality Test and the Primary Predicate Device: Fertell Male Fertility Test

Indications for Use – The SwimCount™ Sperm Quality Test is a qualitative test that detects sperm concentration above or below 5,000,000 Progressive Motile Sperm Cells per mL (PMSCs/mL). The test is intended for use as an aid in the determination of a man's fertility status. For *in vitro,* over-the-counter use.

The number of progressively motile sperm cells is only one factor that contributes to a male's fertility status. The SwimCount™ Sperm Quality Test does not provide a complete evaluation of a

male's fertility status. Sperm concentration and semen volume are only two factors that could impact a man's fertility status and time to pregnancy. For a comprehensive assessment of male fertility status, please consult a physician.

The concentration of progressively motile sperm cells (PMSCs) has consistently been shown to be the most predictive factor with regards to outcome. Around 64% of studies suggest that a reasonable chance of success with artificial insemination requires at least $5x10^6$ motile sperm and this is supported by the WHO's revised reference range for natural conception. (*Tomlinson et al.* Human Fertility, 2013; 16(3): 175–193).

The SwimCount™ Sperm Quality Test and the Primary Predicate Device both measure the concentration of progressively motile sperms in a fresh semen sample. The difference is that the SwimCount™ Sperm Quality Test has a cut-off level of 5,000,000 PMSCs/mL and the Primary Predicate Device has a cut-off value of 10,000,000 PMSCs/mL. The Primary Predicate Device is derived from the WHO 4th edition guidelines 1999 lower reference level and also mentioned as the reference in their 510(k) decision summary.

The 10,000,000 PMSCs/mL calculation is derived from WHO 4th edition guidelines 1999 as follows:
Total sperm concentration per mL of 20 M x 50% (progressive motile sperm cells) = 10 M PMSCs/mL.

For the SwimCount™ Sperm Quality Test we have used the same method of calculation, however, based on and derived from the WHO 5th edition guidelines 2010 as follows:

The SwimCount™ Sperm Quality Test has a primary cut-off Level of 5 M PMSCs/mL which is derived from WHO's 5th edition guidelines 2010, where in section 2.5.4. it is stated that "The lower reference limit for total motility (PR + NP) is 40% (5th centile, 95% CI 38-42).

"The lower reference limit for **progressive motility (PR) is 32%** (5th centile, 95% CI 31–34).

The primary cut-off value is calculated using the WHO 5th edition section 2.8.6.: "The lower reference limit for sperm concentration spermatozoa is 15 x 10^6 spermatozoa per mL (5th centile, 95% CI 12-16 x 10^6).

The above WHO 5th edition clinical method of calculating the lower reference cut-off value for Progressive Motile Sperm Cells (PMSCs)/mL is then calculated as follows:

Total sperm concentration per mL of 15 M x 32% = 4.8 M PMSCs/mL which is rounded to 5 M PMSCs/mL.

As mentioned, the difference in the %-level to be used is due to SwimCount™ Sperm Quality Test using the latest WHO guidelines and whereas the Primary Predicate Device uses an older WHO version (4th edition guidelines 1999).

Please see below a comparison table of the Lower Reference Levels when calculations are based on the WHO 5th edition guidelines 2010 and the WHO 4th edition guidelines 1999:

Table 2. Lower Reference Limits (WHO 2010) and Reference Value (WHO 1999) for Semen Characteristics

Parameter	Lower Reference Limits (WHO 2010)	Reference Value (WHO 1999)
Semen Volume	1.5 ml	≥ 2.0 ml
Sperm Concentration	15 million sperm/ ml	≥ 20 million sperm/ ml
Progressive Motility	32%	≥ 50%*
Total Motility	40%^	n/a
Vitality	58% live	≥ 75% live
Morphology (Strict criteria)	4% normal form	(≥ 15% normal form)#

*Grade a + b according to the WHO 1999 manual.
^Progressive motile + non-progressive motile sperm according to the WHO 2010 manual.
#No actual value given. Value was concluded from multi-centre studies.

Reference: https://specialty.mims.com/topic/semen-analysis---what-a-clinician-should-know-my?topic-grouper=cme

The difference in indications for use does not raise any new issues of safety and effectiveness.

Assay Principle - The dye used in the SwimCount™ Sperm Quality Test stains the mitochondria of the spermatozoa and works by entering the mitochondria where the dye is cleaved to a colored product (only in living cells) by an enzyme. In practicality the color changes from yellow to purple/blue and the darker the purple/blue color equals a higher sperm detection level. The Primary Predicate device's assay test unit is positioned onto the liquefied sample and the pressing of a button releases a solution of sodium hyaluronate buffer solution over the semen sample and starts heating the fluid to 37ºC. Motile sperm swim-up through the sodium hyaluronate for 30 minutes before a valve is opened, by turning a knob, allowing the buffer solution, and motile sperm present, to flow along a capillary channel. Anti-CD59 monoclonal antibody that is conjugated with colloidal gold is released from an absorbent pad in the channel and reacts with the sperm forming an immunocomplex of gold-labeled sperm. The fluid containing this complex, flows onto a nitrocellulose strip where the gold-labeled sperm are trapped, forming a red line. Unreacted conjugate is washed from the strip by the flow of excess buffer. The appearance of a clear red line (test result) indicates motile sperm in the semen sample at a concentration of ≥ 10 M/mL.
The differences in assays raise no new issues of safety and effectiveness.

Test Temperature - The SwimCount™ Sperm Quality Test's is performed at ambient temperature whereas the Primary Predicate Device is performed at 37° Celsius.

Reading Results - The SwimCount™ Sperm Quality Test provides a color chart with 2 possible outcomes; 1) Light Purple/Blue = LOW Sperm Quality = below 5,000,000 PMSCs/mL and 2) Purple/Blue = NORMAL Sperm Quality = above 5,000,000 PMSCs/mL. The Primary Predicative device provides a clear red line (test result) which indicates motile sperm in the semen sample at a concentration of ≥ 10 M/mL. This level is indicative of normally expected motile sperm concentrations.

The differences in reading results raise no new issues of safety and effectiveness.

Non-Clinical Performance Testing

A series of studies were performed that evaluated the traditional laboratory performance characteristics; a summary of each study follows:

Repeatability/Reproducibility
Our precision study (repeatability/reproducibility) was carried out by three operators using three SwimCount™ Sperm Quality Test batches (Operator 1 using SwimCount™ Sperm Quality Test batch 1; Operator 2 using SwimCount™ Sperm Quality Test Batch 2 and Operator 3 using SwimCount™ Sperm Quality Test Batch 3), two replicates per run and two runs per timepoint i.e. 3 x 2 x 2 = 12 samples per time adding up to a total of 36 replicates per sperm concentration (3 time periods). The three Operators were placed at three different locations.

Repeatability
The repeatability (same PMSCs/mL and device lot/operator/location) is shown in the table below (all data at T=30, i.e. 30 minutes after collection of the semen samples):

0 M PMSCs/mL	**Correct**	**Number of tests**	**% correct**
Operator 1	4	4	100%
Operator 2	4	4	100%
Operator 3	4	4	100%
SUM	**12**	**12**	**100%**

1.9 M PMSCs/mL	**Correct**	**Number of tests**	**% correct**
Operator 1	4	4	100%
Operator 2	4	4	100%
Operator 3	4	4	100%
SUM	**12**	**12**	**100%**

4.1 M PMSCs/mL	Correct	Number of tests	% correct
Operator 1	3	4	75%
Operator 2	4	4	100%
Operator 3	4	4	100%
SUM	**11**	**12**	**91,7%**

6.2 M PMSCs/mL	Correct	Number of tests	% correct
Operator 1	4	4	100%
Operator 2	4	4	100%
Operator 3	4	4	100%
SUM	**12**	**12**	**100%**

8.4 M PMSCs/mL	Correct	Number of tests	% correct
Operator 1	4	4	100%
Operator 2	4	4	100%
Operator 3	4	4	100%
SUM	**12**	**12**	**100%**

10.1 M PMSCs/mL	Correct	Number of tests	% correct
Operator 1	4	4	100%
Operator 2	4	4	100%
Operator 3	4	4	100%
SUM	**12**	**12**	**100%**

97.2 M PMSCs/mL	Correct	Number of tests	% correct
Operator 1	4	4	100%
Operator 2	4	4	100%
Operator 3	4	4	100%
SUM	**12**	**12**	**100%**

Overall	Correct	Number of tests	% correct
Operator 1	27	28	96.4%
Operator 2	28	28	100%
Operator 3	28	28	100%
SUM	**83**	**84**	**98.8%**

The repeatability was found to vary between 75% to 100%. Operator 1 misjudged one sample at 4.1 M PMSCs/mL and as this sample is very close to the cut-off value of 5.0 M PMSCs/mL it is concluded, that the repeatability of the SwimCount™ Sperm Quality Test is highly satisfactory.

Reproducibility
The reproducibility of the three operators/batches and locations was very good, but the raw data indicates, that there was a trend towards reduced reproducibility over time.

A new study was performed. This time the actual progressive motile sperm concentration was determined by conventional microscopy at each time points 30 and 60 minutes were investigated.

Semen Sample PMSC Concentration Levels		30 min. after collection	60 min. after collection
0 M PMSCs/mL	**Actual PMSC concentration (counted in a Microscope)**	0	0
	Reproducibility of SwimCount™ Sperm Quality Test	100%	100%
1.7 M PMSCs/mL	**Actual PMSC concentration (counted in a Microscope)**	1.7 M	1.7 M
	Reproducibility of SwimCount™ Sperm Quality Test	100%	100%
3.9 M PMSCs/mL	**Actual PMSC concentration (counted in a Microscope)**	3.9 M	3.9 M
	Reproducibility of SwimCount™ Sperm Quality Test	100%	100%
6.2 M PMSCs/mL	**Actual PMSC concentration (counted in a Microscope)**	6.2 M	6.2 M
	Reproducibility of SwimCount™ Sperm Quality Test	100%	100%
9.1 M PMSCs/mL	**Actual PMSC concentration (counted in a Microscope)**	9.1 M	9.1 M
	Reproducibility of SwimCount™ Sperm Quality Test	100%	100%
11.4 M PMSCs/mL	**Actual PMSC concentration (counted in a Microscope)**	11.4 M	11.4 M
	Reproducibility of SwimCount™ Sperm Quality Test	100%	100%
116.5 M PMSCs/mL	**Actual PMSC concentration (counted in a Microscope)**	116.5 M	116.5 M
	Reproducibility of SwimCount™ Sperm Quality Test	100%	100%

Conclusion
It is concluded, that the Reproducibility of the SwimCount™ Sperm Quality Test is very good when analyzing the semen samples within 60 minutes after collection.

Semen Sample Stability Study

Semen Sample PMSC Concentration Levels		30 min. after collection	60 min. after collection
0 M PMSCs/mL	**Actual PMSC concentration (counted in a Microscope)**	0	0
1.7 M PMSCs/mL	**Actual PMSC concentration (counted in a Microscope)**	1.7 M	1.7 M
3.9 M PMSCs/mL	**Actual PMSC concentration (counted in a Microscope)**	3.9 M	3.9 M
6.2 M PMSCs/mL	**Actual PMSC concentration (counted in a Microscope)**	6.2 M	6.2 M
9.1 M PMSCs/mL	**Actual PMSC concentration (counted in a Microscope)**	9.1 M	9.1 M
11.4 M PMSCs/mL	**Actual PMSC concentration (counted in a Microscope)**	11.4 M	11.4 M
116.5 M PMSCs/mL	**Actual PMSC concentration (counted in a Microscope)**	116.5 M	116.5 M

As can be seen from the above table, using the produced semen sample within 60 minutes of producing the sample the PMSC concentrations are stable.

Because of the obtained results it is emphasized in the SwimCount™ Sperm Quality Test Instructions for Use that the sperm sample should be analyzed 30-60 minutes after semen collection.

Evaluation of Test Performance. Cut-off level.

A pooled semen sample from sperm donors was diluted with semen plasma to progressive motile sperm concentrations of 3.9 M, 4.0 M, 5.0 M, 6.0 M, and 6.2 M PMSCs/mL. Each concentration was tested in 40 replicates. The 4.0 M PMSCs/mL, 5.0 M PMSCs/mL and 6.0 M PMSC/mL concentrations were tested on two SwimCount™ Sperm Quality Test lots (i.e. 80 replicates per sample). The results support the 5.0 M PMSCs/mL cut-off level.

Concentration (PMSCs/mL)	Percent positive (Positive/Total)	Percent negative (Negative/Total)
3.9 M	0 (0/40)	100 (40/40)
4.0 M	7.5 (6/80)	92.5 (74/80)
5.0 M	55.0 (44/80)	45.0 (36/80)
6.0 M	90.0 (72/80)	10.0 (8/80)
6.2 M	100 (40/40)	0 (0/40)

Analytical Specificity (interference study)

The purpose of this study is to identify potential cross-reactivity and interference substances and to investigate if any of these interfere with the test result.

Substances in this context are defined as substances contaminating the sample leading to faulty results.

Such substances include:

1. Bacteria present on skin surfaces and in the sample cup. As model bacteria a gram-positive and a gram-negative bacteria strain are included and in addition microorganisms responsible for sexually transmitted diseases (Neisseria gonorrhoeae and Chlamydia trachomatis) was tested. The concentration tested is set to 10^4 bacteria per mL, as bacteriospermia is defined as > 10^3 bacteria per mL by WHO.
2. Saliva and urine which potentially may contaminate the sperm sample. The tested concentration is set to 10%, which is far above the theoretical contamination concentration.
3. Blood contamination (hematospermia) is very seldom found in semen samples (4) but was investigated at a spike concentration of 1% which corresponds to 10^7 Red Blood cells (RBC)/ml. The concentration of RBC in blood is approximately 10^9 RBC/mL.
4. Possible interfering substances from infections in glands and ureter was investigated using 5 x 10^6 White Blood Cells /mL. The concentration of WBC in blood is approximately 10^6 WBC/mL.
5. Hormones were tested in 10 x the upper reference concentrations found in male serum.

Overview of cross-reactivity and interfering testing of the SwimCount™ Sperm Quality Test

Substance	Source and catalog no.	Test concentration/mL
Gram positive bacteria: Staphylococcus epidermis	ATCC 14990	10^4
Gram negative bacteria: Escherichia coli	ATCC 35218	10^4
Neisseria gonorrhoeae	ATCC 19424	10^4
Chlamydia trachomatis	ATCC VR-885	10^4
Urine	-	10 %
Saliva	-	10 %
Red Blood Cells (RBC)	Fractionated from donor blood at Odense University Hospital, Denmark	10^7
White Blood Cells (WBC)	Fractionated from donor blood at Odense University Hospital, Denmark	5×10^6
D-Norgestrel	Cayman Chemical, Cat no. 10006317	10 ng/mL
β-Estradiol	Sigma E8875	600 pg/mL
Testosterone	Acros Organics 164410050	120 ng/mL

The test was done in triplicate. Each potential interfering substance was spiked in semen samples from vasectomized men (containing semen plasma, only) to investigate any additive effect of interfering substance and in semen samples containing approximately 20 M progressive spermatozoa/mL to investigate any negative effect.

The following substances were identified as substances that may interfere on the SwimCount™ Sperm Quality Test result:

- Urine
- Red Blood Cells (RBC)
- White Blood Cells (WBC)

Urine, Red Blood Cells (RBC) and White Blood Cells (WBC) were included as possible interfering substances in the SwimCount™ Sperm Quality Test Instructions for Use.

Substances which have been identified NOT to interfere with the test:

- Hormones (D-Norgestrel, B-Estradiol and Testosterone)
- Microorganism (Staphylococcus epidermis, Escherichia coli, Neisseria gonorrhoeae,

Chlamydia trachomatis)
- Saliva

Summary of results of the Multi-Center Clinical Study of the SwimCount™ Sperm Quality Test

MotilityCount ApS conducted a Multi-Center Clinical Study at 4 different sites in Denmark (2), Spain (1) and Turkey (1) of the SwimCount™ Sperm Quality Test.
The subjects participating in this study were males attending fertility clinics and donors from a sperm bank with the following Age Brackets:

Multi-Center Clinical Study of the SwimCount™ Sperm Quality Test - No. of Patients per Age Bracket and Category												
		Number of Samples			Number of Samples excluded							Total No. of Net Samples
Age Bracket	Gender	LOW Sperm Quality ~ <5 M PMSCs/mL	NORMAL Sperm Quality ~ ≥5 M PMSCs/mL	Total No. of Samples	< 2 days Abstinence Period	Globospermia	Haematospermia	Leucospermia	Samples <0.5 mL	Samples too viscous	Total Corrected	
0-20	Male	3	17	20							0	20
21-30	Male	23	84	107	1	1	1			1	4	103
31-40	Male	27	115	142	3			5	1	1	10	132
41-58	Male	10	44	54					1		1	53
Total		**63**	**260**	**323**	**4**	**1**	**1**	**5**	**2**	**2**	**15**	**308**

The objective of the Multi-Center Clinical Study was to investigate the performance of the SwimCount™ Sperm Quality Test and compare the test results to the results obtained by standard microscopy.

Results - The SwimCount™ Sperm Quality Test appeared as a useful tool for male fertility assessment. The results obtained were compatible with those obtained with conventional sperm analysis. A Sensitivity result of 95.83% and a Specificity result of 90.68% and an Accuracy of 91.88% was obtained based on 308 semen samples.

SwimCount™ Sperm Quality Test – Sensitivity and Specificity for each individual site:

Center 1 (N=52) - Fertility Clinic Ciconia - Denmark

	Manual Sperm Count Reference	
SwimCount™ Sperm Quality Test	LOW (< 5 M PMSCs/mL)	NORMAL (≥ 5 M PMSCs/mL)
LOW (< 5 M PMSCs/mL)	7	4
NORMAL (≥ 5 M PMSCs/mL)	1	40
		95% Conf. interval
Sensitivity	87.50%	47.35%-99.68%
Specificity	90.91%	78.33%-97.47%

Center 2 (N=135) - Fertility Clinic IVI - Spain

	Manual Sperm Count Reference	
SwimCount™ Sperm Quality Test	LOW (< 5 M PMSCs/mL)	NORMAL (≥ 5 M PMSCs/mL)
LOW (< 5 M PMSCs/mL)	38	14
NORMAL (≥ 5 M PMSCs/mL)	0	83
		95% Conf. interval
Sensitivity	100.00%	90.75%-100.00%
Specificity	85.57%	76.97%-91.88%

Center 3 (N=91) - Nordic Cryo Bank/European Sperm Bank - Denmark

	Manual Sperm Count Reference	
SwimCount™ Sperm Quality Test	LOW (< 5 M PMSCs/mL)	NORMAL (≥ 5 M PMSCs/mL)
LOW (< 5 M PMSCs/mL)	16	3
NORMAL (≥ 5 M PMSCs/mL)	1	71
		95% Conf. interval
Sensitivity	94.12%	71.31%-99.85%
Specificity	95.95%	88.61%-99.16%

Center 4 (N=30) - Acibadem Fulya Hospital - Turkey

	Manual Sperm Count Reference	
SwimCount™ Sperm Quality Test	LOW (< 5 M PMSCs/mL)	NORMAL (≥ 5 M PMSCs/mL)
LOW (< 5 M PMSCs/mL)	8	1
NORMAL (≥ 5 M PMSCs/mL)	1	20
		95% Conf. interval
Sensitivity	88.89%	51.75%-99.72%
Specificity	95.24%	76.18%-99.88%

Multi-Center Clinical Test - Calculation based on Line Data

	Manual Sperm Count Reference	
SwimCount™ Sperm Quality Test	***LOW (<5 M PMSCs/mL)***	***NORMAL (≥5 M PMSCs/mL)***
LOW (<5 M PMSCs/mL)	69	22
NORMAL (≥5 M PMSCs/mL)	3	214
	(4.17% false negative)	(9.32% false positive)
		95% Conf. Interval
Sensitivity	**95.83%**	88.30%-99.13%
Specificity	**90.68%**	86.23%-94.07%
Accuracy*	**91.88%**	89.90%-95.81%

Total No. of Semen Samples	**323**
Othervise exluded for analysis	15
Included Net No. of Semen Samples	**308**

***Accuracy Calculation is based on the following formula: ((69+214)/(69+214+22+3))x100 = 91.88%**

Summary of results of the SwimCount™ Sperm Quality Test from the Lay-User Usability Study

81 Lay-Users participated in the SwimCount™ Sperm Quality Test of the Lay-User Usability Study and were asked to provide their opinion of the test, labelling and interpreting the result of the test. This was accomplished via a Questionnaire including 18 Questions.

The aim of the Lay-User Usability study was to demonstrate and clarify that the SwimCount™ Sperm Quality Test is simple, accurate and poses no significant risk of erroneous results.

The Lay-User Usability Study was divided into two main parts:

A. Lay-User's ability to perform the test as intended and described in the SwimCount™ Sperm Quality Test Instructions for Use

   and

B. That Lay-Users can interpret the SwimCount™ Sperm Quality Test result correctly

Consumer Use Study

Lay-Users who participated in the Lay-User Usability Study (Consumer Use Study) provided their opinion on a scale ranging from 'Very Easy'=5 to 'Very Difficult'= 1 of the test, labelling and results.

This was accomplished via a Questionnaire and the 6 most relevant out of 18 questions posed to the 81 Lay-User participants are provided in the tables below along with the results.

Question # 1			
FOLLOWING AND UNDERSTANDING the SwimCount™ Sperm Quality Test Instructions for Use			
#	QUESTION	NUMBER OF PARTICIPANTS RESPONDING	RESPONSE %
5	Very Easy	43	53.09
4	↑	35	43.21
3	↕	3	3.70
2	↓	0	0.00
1	Very Difficult	0	0.00
	TOTAL	81	100%

Question # 2			
APPLYING THE SEMEN SAMPLE correctly to the device according to the SwimCount™ Sperm Quality Test Instructions for Use			
#	QUESTION	NUMBER OF PARTICIPANTS RESPONDING	RESPONSE %
5	Very Easy	52	64.20
4	↑	24	29.63
3	↕	5	6.17
2	↓	0	0.00
1	Very Difficult	0	0.00
	TOTAL	81	100%

Question # 3			
FINDING THE RESULT WINDOW according to the SwimCount™ Sperm Quality Test Instructions for Use			
#	QUESTION	NUMBER OF PARTICIPANTS RESPONDING	RESPONSE %
5	Very Easy	59	72.84
4	↑	14	17.28
3	↕	6	7.41
2	↓	1	1.23
1	Very Difficult	1	1.23
	TOTAL	81	100.0%

Question # 4		
WHAT DOES A LIGHT BLUE COLOR RESULT mean according to the SwimCount™ Sperm Quality Test Instructions for Use		
QUESTION	NUMBER OF PARTICIPANTS RESPONDING	RESPONSE %
LOW Sperm Quality (<5 M PMSCs/mL)	81	100.00 (correct answer)
NORMAL Sperm Quality (≥5 M PMSCs/mL)	0	0.00
TOTAL	81	100%

Question # 5		
WHAT DOES A DARK BLUE COLOR RESULT mean according to the SwimCount™ Sperm Quality Test Instructions for Use		
QUESTION	NUMBER OF PARTICIPANTS RESPONDING	RESPONSE %
LOW Sperm Quality (<5 M PMSCs/mL)	0	0.00
NORMAL Sperm Quality (≥5 M PMSCs/mL)	81	100.00 (correct answer)
TOTAL	81	100%

Question # 6			
DETERMINE the EASE-OF-USE WHEN READING YOUR SwimCount™ Sperm Quality Test Result			
#	QUESTION	NUMBER OF PARTICIPANTS RESPONDING	RESPONSE %
5	Very Easy	43	53.09
4	↑	28	34.57
3	↕	6	7.41
2	↓	2	2.47
1	Very Difficult	2	2.47
	TOTAL	81	100%

The overall summary of results of the SwimCount™ Sperm Quality Test Lay-User Usability Study was as follows:

- A very good and easy-to-use device (some even called it Great, Super easy and Simple) with a score of 4.33 out of 5 to read their own SwimCount™ Sperm Quality Test result
- 79 out of the 81 participants read their own result correctly
- Out of the 81 read results 15 results were LOW (<5 M PMSCs/mL) and 66 were NORMAL (≥5 M PMSCs/mL) as judged by Laboratory Professionals
- The Lay-Users uploaded a picture of their own SwimCount™ Sperm Quality Test result in the survey
- Thus, in the Lay-User study carried out at home with the Lay-User's own semen sample, there was a 97.53% agreement (% of Correct Calls) between the SwimCount™ Sperm Quality Test result read by the Lay-User at home and those obtained by Laboratory Professionals reading and analyzing the same uploaded picture of the SwimCount™ Sperm Quality Test result

SwimCount™ Sperm Quality Test - % of Correct Calls - Consumer Use Study								
Study	**No. of Lay-Users**	**Total No. of Samples**	**Total No. of Responses per Lay-User/ID**	**Corrected for errors**	**Total No. of Net Responses from Lay-Users/ID**	**Correct Answers**	**Not Correct Answers**	**% of Correct Calls by Lay-Users**
Consumer Use Study - Lay User Study (Year 2018)	**81**	**81**	**1**	**0**	**81**	**79**	**2**	**97.53%**

- Nothing was confusing as the Pre-Performing phase of the SwimCount™ Sperm Quality Test had 100% of the Participants reading and fully understanding the SwimCount™ Sperm Quality Test Instructions for Use
- Regarding the Post Reading of the SwimCount™ Sperm Quality Test Instructions for Use 100% of the Participants could perform the SwimCount™ Sperm Quality Test in a satisfactory way

Consumer Interpretation Study

In addition to the Consumer Use Study a Consumer Interpretation Study was carried out.

81 Participants were asked to provide their opinion on 10 SwimCount™ Sperm Quality Test result pictures (N=810). This was accomplished via a Questionnaire including 10 Pictures of a SwimCount™ Sperm Quality Test result each including both LOW and NORMAL Sperm Quality Test Results.

791 out of the 810 pictures were read correctly and 19 pictures were not read correctly by the participants equal to 97.65% of correct calls by lay-users.

Consumer Interpretation Study - Lay User Study		
	Manual Sperm Count Reference	
SwimCount™ Sperm Quality Test	***LOW (<5 M PMSCs/mL)***	***NORMAL (≥5 M PMSCs/mL)***
LOW (<5 M PMSCs/mL)	322	17
NORMAL (≥5 M PMSCs/mL)	2	469
	(0.62% false negative)	(3.50% false positive)
		95% Conf. Interval
Correct Calls by Lay-Users	**97.65%**	96.70%-98.81%
Total Number of Participants	**81**	
Pictures Read Per Participant	10	
Total Number of Pictures Read	**810**	

Conclusions from Non-clinical and Clinical testing

The data from the Non-clinical and Clinical testing indicates that the SwimCount™ Sperm Quality Test is safe and effective for its intended use.