May 2, 2025

Medical Electronic Systems Ltd.
Taly Vider Cohen
Regulatory Affairs and IP Director
Alon Hatavor St. 20
Caesarea, 3088900
Israel

Re: K243114
Trade/Device Name: SQA-iOw Sperm Quality Analyzer
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: POV
Dated: January 30, 2025
Received: January 30, 2025

Dear Taly Vider Cohen:

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 and Part 809); 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,

Min Wu -S

Min Wu, Ph.D.
Branch Chief
Division of Immunology and Hematology Devices
OHT7: Office of In Vitro Diagnostics
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)*
K243114

Device Name
SQA-iOw Sperm Quality Analyzer

Indications for Use *(Describe)*
The SQA-iOw Sperm Quality Analyzer is an automated analyzer intended for in-vitro diagnostic use to determine the following parameters in semen:
Measured parameters:
• Sperm Concentration/ Total Sperm Concentration, millions/mL
• Motile Sperm Concentration (MSC), millions/mL
• Progressively Motile Sperm Concentration (PMSC), millions/mL (combines Rapidly and Slowly Progressive Motile Sperm Concentration, millions/mL)
• Normal Forms (% Normal Morphology), %
Derived parameters:
• Total Motility / Total Motile (PR + NP), %
• Progressive Motility (PR), % (combines Rapidly and Slowly Progressive, %)
• Non-Progressive (NP), %
• Immotile (IM), %
The SQA-iOw is intended for CLIA Waived settings. The SQA-iOw does not provide a comprehensive evaluation of a male's fertility status and is intended for in vitro use only.

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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Date: 02.MAY.2025

SQA-iOw 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

807.92 (a)(1):

Name: Medical Electronic Systems, LTD

Address: ALON HATAVOR ST. 20 ZONE 6
CAESAREA INDUSTRIAL PARK
CAESAREA, 38900, ISRAEL

Phone: 972 54 209-1712
Contact: Ms. Taly Vider Cohen

807.92 (a)(2): Device name, trade name and common name, and Classification

Trade Name: SQA-iOw Sperm Quality Analyzer

Common Name: SQA-iOw Sperm Quality Analyzer

Classification: Class II, POV
21 CFR 864.5220

807.92 (a)(3): Identification of the legally marketed predicate devices

SQA-iOw Sperm Quality Analyzer is substantially equivalent to a predicate device, the SQA-V sperm analyzer, (MES Ltd., Israel), cleared under K021746, September 20, 2002. Both of these testing devices utilize human sperm to measure a variety of male fertility factors.

807.92 (a)(4): Device Description

The SQA-iOw Sperm Quality Analyzer is a PC-based analytical medical device that tests human semen samples. The device works with a computer application that manages the device, and information related to the patient, the sample, the test results and the facility.

After collection and preparation, 0.6 mL of semen sample is aspirated into a disposable SQA capillary sample delivery system and inserted into the SQA-iOw measurement chamber. The testing process takes approximately 75 seconds. The system performs an automatic self-test and auto-calibration upon start up, and checks device stability before each sample is run.

The SQA-iOw Sperm Quality Analyzer utilizes proprietary software code to both perform analysis of semen parameters and present those results on the user interface. This software is installed on a PC as a cloud-based application ("app") and is designed to perform all functions and features of the SQA-iO device, controlled by the user through a proprietary graphical user interface (GUI).

The SQA-iOw Sperm Quality Analyzer software analyzes semen parameters using signal processing technology. Sample testing is performed by capturing electrical signals as sperm moves through a light source in the SQA-iO optical block. These light disturbances are converted into electrical signals which are then analyzed by the SQA-iOw software. The SQA-iOw software applies proprietary algorithms to interpret and express these electrical signals and report them as various semen parameters.

The SQA-iOw Sperm Quality Analyzer package provides the SQA-iOw device and USB cable. SQA disposable capillaries, cleaning kits and related testing supplies and test kits are supplied individually.

807.92 (a)(5): Intended Use

The SQA-iOw Sperm Quality Analyzer is an automated analyzer intended for in-vitro diagnostic use to determine the following parameters in semen:

Measured parameters:

- Sperm Concentration/ Total Sperm Concentration, millions/mL
- Motile Sperm Concentration (MSC), millions/mL
- Progressively Motile Sperm Concentration (PMSC), millions/mL (combines Rapidly and Slowly Progressive Motile Sperm Concentration, millions/mL)
- Normal Forms (% Normal Morphology), %

Derived parameters:

- Total Motility / Total Motile (PR + NP), %
- Progressive Motility (PR), % (combines Rapidly and Slowly Progressive, %)
- Non-Progressive (NP), %
- Immotile (IM), %

The SQA-iOw is intended for CLIA Waived settings. The SQA-iOw does not provide a comprehensive evaluation of a male's fertility status and is intended for in vitro use only.

807.92 (a)(6): Technological Similarities and Differences to the Predicate

SQA-iOw Sperm Quality Analyzer is substantially equivalent to the predicate device; SQA-V Sperm Quality Analyzer, (MES Ltd., Israel), cleared under K021746. The SQA-iOw is substantially equivalent in terms of general intended use, sample type, male fertility factor measurements, and in vitro use. The various device features are compared in the table below.

SQA-iOw vs. SQA-V Predicate

Element	New product SQA-iOw Sperm Quality Analyzer	Predicate SQA-V: 510(k) K021746
Intended use	See "intended use" section above.	The SQA-V is a point-of-care, in vitro use, electro-optical medical device with on-screen visualization for semen analysis performed by healthcare professionals (trained lab technicians- device is CLIA moderate). The SQA-V does not provide a comprehensive evaluation of a male's fertility status.
Intended User	Healthcare professionals (CLIA waived, moderate, and high complexity settings)	Healthcare professionals (trained lab technicians, CLIA moderate or high complexity)

Element	New product SQA-iOw Sperm Quality Analyzer	Predicate SQA-V: 510(k) K021746
Semen parameters	The SQA-iOw reports the following directly measured quantitative semen parameters: 1. Sperm Concentration/ Total Sperm Concentration, millions/mL 2. Motile Sperm Concentration (MSC), millions/mL 3. Progressively Motile Sperm Concentration (PMSC), millions/mL (combines Rapidly and Slowly Progressive Motile Sperm Concentration, millions/mL) 4. Normal Forms (% Normal Morphology), % The SQA-iOw also reports the following derived semen parameters: 5. Total Motility / Total Motile (PR + NP), % 6. Progressive Motility (PR), % (combines Rapidly and Slowly Progressive, %) 7. Non-Progressive (NP), % 8. Immotile (IM), %	The SQA-V reports the same Semen Parameters
WHO compliance	WHO 6	WHO 4/ WHO 5
Sample type	Human semen	Same
Male fertility factor	Yes	Same
Technology	Desk-top unit consists of a light source and optical sensors, connected to a PC that runs the software containing algorithms for the assessment of semen parameters. This software is installed on the user's PC as a cloud-based application. See additional explanations in the discussion section below.	Desk-top unit consists of a light source, optical sensors, built-in video microscopy and an internal computer containing algorithms for the assessment of semen parameters.
Testing capillary	SQA-V testing capillary	Same
External controls	Use of QwikCheck Beads (cleared under K041600) for performing quality control	Same

(b)(1): Brief Description of Nonclinical Data

- Linearity/dynamic ranges (Assay measuring range)- See K220828.
- Analytical specificity (interference)- See K220828.
- Sample stability- see K220828.
- Analytical sensitivity (detection limits: limits of blank and detection/quantitation)- See K220828.

807.92 (b)(2): Brief Description of Clinical Data

Clinical Precision

MES performed two waived-user precision studies as follows:

1. Precision using control material
2. Precision using native samples.

1. CLIA Waived user Precision study using control material

Objective and Study Design

To estimate precision/repeatability of the SQA-iOw device based on the CLSI EP05-A3 standard, a study was designed as follows: 3 sites x 9 users (3 per site) over 3 days per site x 3 levels x 10 replicates of each level (5 runs in duplicate) = 270 measurements in total. Three levels of bead controls (same lots across sites) and three lots of capillaries (different lots across sites) were used. Data analyses included ANOVA analysis with the following components: within-run, between-operator, between-day, and between-site repeatability using standard deviations (SDs) and Coefficients of Variation (CV, %).

Table 1: Controls Level 1

Site	N	Mean	Repeatability (Within-run)		Between-day		Between-run/ Operator		Between site / instrument		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
All sites combined	90	47.8	0.12	0.24%	0.40	0.83%	0.35	0.74%	0.69	1.45%	0.88	1.84%

Table 2: Controls Level 2

Site	N	Mean	Repeatability (Within-run)		Between-day		Between-run/ Operator		Between site / instrument		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
All sites combined	90	24.9	0.06	0.23%	0.57	2.28%	0.45	1.83%	0.68	2.73%	1.00	4.01%

Table 3: Negative Control

Site	N	Mean	Repeatability (Within-run)		Between-day		Between-run/ Operator		Between site / instrument		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
All sites combined	90	0.0	0.00	0.00%	0.00	0.00%	0.00	0.00%	0.00	0.00%	0.00	0.00%

Conclusion
The StDev and %CV met the acceptance criteria for the three levels.

2. CLIA Waived user Precision study using native samples

Objective and Study Design

To determine precision of the SQA-iOw device based on CLSI EP05-A3 guidance, as follows, across two sites: 9 total native semen samples x 2 reps per sample x 3 users/site x 4 time points = 216 measurements total, 24 results per sample. Precision analysis included within-run, between-operator standard deviations (SD) and Coefficients of Variation (CV, %), and total imprecision (reproducibility) using the estimated components.

Results

The following precision results were obtained by the waived users testing native semen samples using SQA-iOw Waiver devices:

Table 4: SQA-iOw Sperm Concentration Precision

Sample #	N	Mean	Repeatability		Between-operator		Total	
			SD	%CV	SD	%CV	SD	%CV
1	24	55.42	1.125	2.0%	0.925	1.7%	1.457	2.6%
2	24	116.88	2.913	2.5%	1.370	1.2%	3.219	2.8%
3	24	88.58	1.601	1.8%	1.773	2.0%	2.389	2.7%
4	24	228.40	1.841	0.8%	3.697	1.6%	4.130	1.8%
5	24	97.63	0.811	0.8%	1.215	1.2%	1.461	1.5%
6	24	15.81	1.316	8.3%	1.807	11.4%	2.236	14.1%
7	24	14.70	0.740	5.0%	1.775	12.1%	1.923	13.1%

Note: SDs are used for low-level samples (<10)

Table 5: SQA-iOw Motile Sperm Concentration (MSC) Precision

Sample #	N	Mean	Repeatability		Between-operator		Total	
			SD	%CV	SD	%CV	SD	%CV
1	24	27.06	0.976	3.6%	0.230	0.9%	1.003	3.7%
2	24	57.63	2.137	3.7%	1.000	1.7%	2.359	4.1%
3	24	41.78	1.367	3.3%	0.428	1.0%	1.433	3.4%
4	24	120.41	3.410	2.8%	2.324	1.9%	4.127	3.4%
5	24	32.43	3.169	9.8%	1.906	5.9%	3.698	11.4%
6	24	1.60	0.000	0.0%	0.000	0.0%	0.000	0.0%
7	24	1.60	0.000	0.0%	0.000	0.0%	0.000	0.0%
8	24	9.42	0.632	6.7%	1.219	12.9%	1.373	14.6%
9	24	4.32	0.627	14.5%	1.684	39.0%	1.797	41.6%

Note: SDs are used for low-level samples (<10)

Table 6: SQA-iOw Progressive Motile Sperm Concentration (PMSC) Precision

Sample #	N	Mean	Repeatability		Between-operator		Total	
			SD	%CV	SD	%CV	SD	%CV
1	24	22.50	0.921	4.1%	0.432	1.9%	1.017	4.5%
2	24	49.03	2.551	5.2%	1.129	2.3%	2.790	5.7%
3	24	33.52	1.535	4.6%	0.447	1.3%	1.599	4.8%
4	24	108.70	3.610	3.3%	2.497	2.3%	4.389	4.0%
5	24	24.69	3.103	12.6%	1.915	7.8%	3.646	14.8%
6	24	0.03	0.041	163.3%	0.014	57.7%	0.043	173.2%
7	24	0.09	0.245	267.2%	0.088	95.8%	0.260	283.9%
8	24	6.80	0.535	7.9%	0.652	9.6%	0.844	12.4%
9	24	2.97	0.538	18.1%	1.083	36.5%	1.209	40.7%

Note: SDs are used for low-level samples (<10)

Table 7: SQA-iOw Morphology Precision

Sample #	N	Mean	Repeatability		Between-operator		Total	
			SD	%CV	SD	%CV	SD	%CV
1	24	7.67	0.707	9.2%	0.354	4.6%	0.791	10.3%
2	24	7.96	0.736	9.2%	0.382	4.8%	0.829	10.4%
3	24	7.08	0.500	7.1%	0.204	2.9%	0.540	7.6%
4	24	9.67	0.408	4.2%	0.479	5.0%	0.629	6.5%
5	24	4.04	0.612	15.2%	0.354	8.7%	0.707	17.5%
6	24	0.13	0.204	163.3%	0.204	163.3%	0.289	230.9%
7	24	0.33	0.764	229.1%	0.289	86.6%	0.816	244.9%
8	24	8.38	0.736	8.8%	0.500	6.0%	0.890	10.6%
9	24	3.50	0.913	26.1%	0.722	20.6%	1.164	33.2%

Note: SDs are used for low-level samples (<10)

Table 8: SQA-iOw Motility Precision

Sample #	N	Mean	Repeatability		Between-operator		Total	
			SD	%CV	SD	%CV	SD	%CV
1	24	48.83	2.290	4.7%	1.145	2.3%	2.561	5.2%
2	24	49.37	2.757	5.6%	1.378	2.8%	3.082	6.2%
3	24	47.24	3.031	6.4%	1.516	3.2%	3.389	7.2%
4	24	52.73	4.404	8.4%	2.202	4.2%	4.924	9.3%
5	24	33.24	2.641	7.9%	1.320	4.0%	2.952	8.9%
6	24	29.66	1.109	3.7%	0.555	1.9%	1.240	4.2%
7	24	31.08	0.955	3.1%	0.478	1.5%	1.068	3.4%
8	24	59.59	3.039	5.1%	1.519	2.5%	3.397	5.7%
9	24	30.91	3.028	9.8%	1.514	4.9%	3.385	11.0%

Table 9: SQA-iOw Progressive Motility Precision

Sample #	N	Mean	Repeatability		Between-operator		Total	
			SD	%CV	SD	%CV	SD	%CV
1	24	40.59	2.219	5.5%	1.110	2.7%	2.481	6.1%
2	24	42.03	2.880	6.9%	1.440	3.4%	3.220	7.7%
3	24	37.93	3.073	8.1%	1.536	4.1%	37.93	3.436
4	24	47.60	4.496	9.4%	2.248	4.7%	5.027	10.6%
5	24	25.31	2.594	10.2%	1.297	5.1%	2.900	11.5%
6	24	0.47	1.111	234.1%	0.556	117.0%	1.243	261.7%
7	24	1.75	1.029	58.7%	0.514	29.3%	1.150	65.6%
8	24	42.97	2.882	6.7%	1.441	3.4%	3.222	7.5%
9	24	21.24	2.852	13.4%	1.426	6.7%	3.189	15.0%

Note: SDs are used for low-level samples (<10)

Table 10: SQA-iOw Non-progressive Motility Precision

Sample #	N	Mean	Repeatability		Between-operator		Total	
			SD	%CV	SD	%CV	SD	%CV
1	24	8.24	2.504	30.4%	1.252	15.2%	2.800	34.0%
2	24	7.34	2.822	38.4%	1.411	19.2%	3.155	43.0%
3	24	9.30	2.930	31.5%	1.465	15.7%	3.276	35.2%
4	24	5.13	3.520	68.6%	1.760	34.3%	3.935	76.7%
5	24	7.93	2.713	34.2%	1.357	17.1%	3.034	38.2%
6	24	29.19	1.758	6.0%	0.879	3.0%	1.966	6.7%
7	24	29.33	1.672	5.7%	0.836	2.8%	1.869	6.4%
8	24	16.62	2.875	17.3%	1.438	8.6%	3.215	19.3%
9	24	9.67	2.850	29.5%	1.425	14.7%	3.187	32.9%

Note: SDs are used for low-level samples (<10)

Table 11: SQA-iOw Immotile Precision

Sample #	N	Mean	Repeatability		Between-operator		Total	
			SD	%CV	SD	%CV	SD	%CV
1	24	51.17	2.290	4.5%	1.145	2.2%	2.561	5.0%
2	24	50.63	2.757	5.4%	1.378	2.7%	3.082	6.1%
3	24	52.76	3.031	5.7%	1.516	2.9%	3.389	6.4%
4	24	47.27	4.404	9.3%	2.202	4.7%	4.924	10.4%
5	24	66.76	2.641	4.0%	1.320	2.0%	2.952	4.4%
6	24	70.34	1.109	1.6%	0.555	0.8%	1.240	1.8%
7	24	68.92	0.955	1.4%	0.478	0.7%	1.068	1.5%
8	24	40.41	3.039	7.5%	1.519	3.8%	3.397	8.4%
9	24	69.09	3.028	4.4%	1.514	2.2%	3.385	4.9%

Conclusion

The StDev and %CV met the acceptance criteria for all reported parameters for the samples.

Method Comparison Study

Objective:

To demonstrate clinical equivalence of the SQA-iOw device operated by WAIVED USERS vs. the SQA-V performed by TRAINED USERS when testing matched native human semen samples.

Study Design:

- Sites: Three U.S. sites
- Waived testing: 9 WAIVED USERS (3 per site).
- Comparative testing: One or more TRAINED OPERATORS per site who are fully trained and considered appropriate for generating reference SQA-V results.
- Sample size: A total of 380 donor semen samples distributed approximately equally across 3 sites and 9 operators and assayed in singleton and in a blinded fashion using both methods.

Parameters for comparison in the clinical studies:

Directly measured parameters:

- Sperm Concentration/ Total Sperm Concentration, millions/ml
- Motile Sperm Concentration (MSC), millions/ml
- Progressively Motile Sperm Concentration (PMSC), millions/ml (combines Rapidly and Slowly Progressive Motile Sperm Concentration, millions/mL)
- Normal Forms (% Normal Morphology), %

Calculated parameters:

- Total Motility / Total Motile (PR + NP), %
- Progressive Motility (PR), % (combines Rapidly and Slowly Progressive, %)
- Non-Progressive (NP), %
- Immotile (IM), %

Data Analysis: Statistical Methods and Acceptance Criteria

Stats: Passing-Bablok regression with "lab results" (SQA-V results obtained by the trained user) on the x-axis. Slopes, y-intercepts, and correlation coefficients, along with the 95% confidence intervals, were reported.

Results:

Table 12: SQA-iOw Intended User vs. SQA-V Expert User

Parameter	N	Range	Intercept (95% CI)	Slope (95% CI)	Correlation (95% CI)
CONCENTRATION, M/mL	380	6.0 – 272.5	-0.05 (-0.4799 to 0.2610)	0.98 (0.9718 to 0.9836)	1.0 (0.9974 to 0.9982)
MOTILITY, %	380	0.0 – 100.0	2.1 (1.2174 to 3.0000)	0.9 (0.9189 to 0.9565)	0.96 (0.9493 to 0.9659)
PROGRESSIVE MOTILITY, %	380	0.0 – 88.0	-0.7 (-1.4516 to 0.0000)	1.0 (0.9286 to 0.9677)	1.0 (0.9683 to 0.9787)
NON-PROGRESSIVE MOTILITY, %	380	0.0 – 30.0	-0.3 (-1.0000 to 0.0000)	1.3 (1.2500 to 1.4000)	0.7 (0.6944 to 0.7850)
IMMOTILE, %	380	0.0 – 99.0	4.0 (3.0417 to 5.0000)	0.9 (0.9200 to 0.9583)	0.9 (0.9130 to 0.9411)
MORPHOLOGY, %	380	0.0 – 22.0	-1.0 (-1.0000 to -0.0455)	1.0 (0.9091 to 1.0000)	1.0 (0.9563 to 0.9706)
MSC, %	380	0.2 – 151.7	0.3 (0.05708 to 0.5580)	0.9 (0.9344 to 0.9571)	1.0 (0.9889 to 0.9925)
PMSC, %	380	0.0 – 139.5	-0.3 (-0.5450 to -0.0968)	0.9 (0.9149 to 0.9364)	1.0 (0.9894 to 0.9929)

807.92 (b)(3): Conclusions from Nonclinical and Clinical Testing

The SQA-iOw testing confirms that the device can be used according to its intended use. The information and data provided in this 510(k) submission identifies no new safety or effectiveness issues for this device type. Therefore, the SQA-iO is safe and performs effectively based on its intended use.