August 7, 2023

Medical Electronic Systems LTD
Taly Cohen
Regulatory Affairs and IP Director
Alon Hatavor 20, Zone 6, Caesarea Industrial Park
Caesarea, 3088900
Israel

Re: K220828
Trade/Device Name: SQA-iO Sperm Quality Analyzer
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated Differential Cell Counter
Regulatory Class: Class II
Product Code: POV
Dated: March 10, 2022
Received: March 22, 2022

Dear Taly 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 (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/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 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 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)*
K220828

Device Name
SQA-iO Sperm Quality Analyzer

Indications for Use *(Describe)*
The SQA-iO Sperm Quality Analyzer is an automated point-of-care in vitro use only medical device for semen analysis performed by healthcare professionals (trained lab technicians). The SQA-iO does not provide a comprehensive evaluation of a male's fertility status.

The SQA-iO provides direct and calculated quantitative measurements for the following parameters:

Directly measured parameters:
- Sperm Concentration, M/mL
- Motile Sperm Concentration (MSC), M/mL
- Progressively Motile Sperm Concentration (PMSC), M/mL (combines Rapid and Slow PMSC, millions/mL)
- Normal Forms (Normal Morphology), %

Calculated parameters:
- Total Motility (PR + NP), %
- Progressive Motility (PR), % (combines Rapidly and Slowly Progressive Motility, %)
- Non-Progressive Motility (NP), %
- Immotile (IM), %
- Functional Sperm Concentration (FSC), millions/mL

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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K220828- 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being 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
FAX: NA
Contact: Ms. Taly Vider Cohen

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

Classification/Trade Name:
SQA-iO Sperm Quality Analyzer

Common Name: SQA-iO Sperm Quality Analyzer

Classification: Class II, POV
21 CFR 864.5220

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

SQA-iO 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 fresh human sperm to measure a variety of male fertility factors.

807.92 (a)(4): Device Description

The SQA-iO 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, 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-iO 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-iO utilizes proprietary software code to both perform analysis of semen parameters and to present those results on the user interface. This software is installed on the user's 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 interface (GUI).

The SQA-iO 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-iO software. The SQA-iO software applies proprietary algorithms to interpret and express these electrical signals and report them as various semen parameters.

The SQA-iO package provides all the supplies necessary to perform semen analysis: SQA-iO device, USB cable, SQA disposable capillaries, and a cleaning kit.

807.92 (a)(5): Intended Use

The SQA-iO Sperm Quality Analyzer is an automated point-of-care in vitro use only medical device for semen analysis performed by healthcare professionals (trained lab technicians). The SQA-iO does not provide a comprehensive evaluation of a male's fertility status.

The SQA-iO provides direct and calculated quantitative measurements for the following parameters:

Directly measured parameters:

- Sperm Concentration, M/mL
- Motile Sperm Concentration (MSC), M/mL
- Progressively Motile Sperm Concentration (PMSC), M/mL (combines Rapid and Slow PMSC, millions/mL)
- Normal Forms (Normal Morphology), %

Calculated parameters:

- Total Motility (PR + NP), %
- Progressive Motility (PR), % (combines Rapidly and Slowly Progressive Motility, %)
- Non-Progressive Motility (NP), %
- Immotile (IM), %
- Functional Sperm Concentration (FSC), millions/mL

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

SQA-iO is substantially equivalent to an FDA-cleared predicate device- SQA-V sperm quality analyzer, (MES Ltd., Israel), cleared under K021746, September 20, 2002. SQA-iO is substantially equivalent to this product in terms of general intended use, sample type, male fertility factor measurements, and in vitro use. Further, the SQA-iO is substantially equivalent to the SQA-V in terms of the assessed parameters.

SQA-iO vs. SQA-V Predicate

Element	New product SQA-iO Sperm Quality Analyzer	Predicate SQA-V: 510(k) K021746
Intended use	The SQA-iO Sperm Quality Analyzer is an automated point-of-care in vitro use medical device for semen analysis performed by healthcare professionals (trained lab technicians). The SQA-iO does not provide a comprehensive evaluation of a male's fertility status.	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).
Semen parameters	The SQA-iO Sperm Quality Analyzer is an automated point-of-care in vitro use only medical device for semen analysis performed by healthcare professionals (trained lab technicians). The SQA-iO does not provide a comprehensive evaluation of a male's fertility status. The SQA-iO provides direct and calculated quantitative measurements for the following parameters: Directly measured parameters: • Sperm Concentration, M/mL	Same

Element	New product SQA-iO Sperm Quality Analyzer	Predicate SQA-V: 510(k) K021746
	• Motile Sperm Concentration (MSC), M/mL • Progressively Motile Sperm Concentration (PMSC), M/mL (combines Rapid and Slow PMSC, millions/mL) • Normal Forms (Normal Morphology), % Calculated parameters: • Total Motility (PR + NP), % • Progressive Motility (PR), % (combines Rapidly and Slowly Progressive Motility, %) • Non-Progressive Motility (NP), % • Immotile (IM), % • Functional Sperm Concentration (FSC), millions/mL	
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.	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.
External controls	Use of QwikCheck Beads (cleared under K041600) for performing quality control	Same

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

Medical Electronic Systems (MES) has conducted a series of analytical (bench) studies in support of the analytical claims of the SQA-iO. These studies were all performed in-house and included evaluations for: precision- Repeatability (Native Sample precision), Precision- Reproducibility (Controls precision), analytical sensitivity (limits of blank and detection/quantitation), linearity/dynamic ranges, analytical specificity (interference), sample stability, and cleaning robustness.

All the studies utilized native human semen samples (including seminal plasma for negative samples), with some samples being manually diluted with seminal plasma to achieve the necessary quantitation ranges. Semen samples were collected following WHO 6th ed. manual guidance for sample handling from consented donors and were assayed in a blinded fashion on the SQA-iO, and in parallel on the SQA-V comparator device, as applicable.

Precision- Repeatability (Native Sample Precision)

Eight samples, spanning low, middle and high levels of five parameters (concentration, motility, MSC, PMSC, and morphology, were assayed in duplicate on five devices over four time-points. Due to the limited stability of semen samples, each "day" in the statistical analysis represented different times of day with

testing at the 0, 20, 40, and 60-minute time points resulting in: 2 replicates x 5 devices x 4 days = 40 replicate results per sample, for each of the five parameters.

Data analyses were performed to provide: within-run, between-run, between-day, between-operator/lot/instrument, and total precision and standard deviations (SDs) and percent coefficients of variation (%CVs) were calculated for each sample.

SQA-iO Sperm Concentration Precision

Concentration			Within-Run		Between-Run		Between-Day		Between-Operator/ Lot/Instrument		Total	
Sample	**N**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
1	40	8.5	0.63	7.4%	0.61	7.2%	0.25	2.9%	0.60	7.1%	0.62	7.3%
2	40	34.5	1.66	4.8%	1.70	4.9%	0.77	2.2%	1.31	3.8%	1.76	5.1%
3	40	45.4	3.25	7.2%	3.30	7.3%	1.66	3.7%	3.09	6.8%	3.46	7.6%
4	40	58.5	3.12	5.3%	3.07	5.2%	1.04	1.8%	2.11	3.6%	3.04	5.2%
5	40	62.2	2.42	3.9%	2.38	3.8%	1.42	2.3%	2.30	3.7%	2.64	4.2%
6	40	181.6	5.25	2.9%	5.35	2.9%	3.42	1.9%	3.83	2.1%	5.87	3.2%
7	40	227.6	5.87	2.6%	6.25	2.7%	5.45	2.4%	3.48	1.5%	7.58	3.3%
8	40	212.9	3.74	1.8%	4.42	2.1%	4.87	2.3%	2.67	1.3%	5.79	2.7%

SQA-iO Motility Precision

Motility			Within-Run		Between-Run		Between-Day		Between-Operator/ Lot/Instrument		Total	
Sample	**N**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
1	40	0.0	0.00	0.0%	0.00	0.0%	0.00	0.0%	0.00	0.0%	0.00	0.0%
2	40	77.0	2.82	3.7%	2.74	3.6%	1.20	1.6%	2.59	3.4%	2.87	3.7%
3	40	62.3	2.62	4.2%	2.59	4.2%	0.74	1.2%	2.27	3.7%	2.54	4.1%
4	40	80.6	0.99	1.2%	1.00	1.2%	0.46	0.6%	0.83	1.0%	1.01	1.3%
5	40	58.0	3.83	6.2%	4.65	7.7%	3.23	5.6%	2.60	4.5%	6.99	12.1%
6	40	43.9	1.81	4.1%	1.99	4.5%	1.18	2.7%	1.37	3.1%	2.04	4.6%
7	40	30.7	2.29	7.5%	2.52	8.3%	2.22	7.2%	0.94	3.1%	3.03	9.9%
8	40	49.9	1.52	3.0%	1.77	3.5%	1.52	3.0%	1.28	2.6%	2.05	4.1%

SQA-iO Motile Sperm Concentration (MSC) Precision

MSC			Within-Run		Between-Run		Between-Day		Between-Operator/ Lot/Instrument		Total	
Sample	**N**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
1	40	2.0	0.00	0.0%	0.00	0.0%	0.00	0.0%	0.00	0.0%	0.00	0.0%
2	40	26.5	1.31	5.0%	1.36	5.1%	1.05	4.0%	0.68	2.6%	1.60	6.0%
3	40	27.9	1.40	5.0%	1.55	5.5%	1.03	3.7%	1.08	3.9%	1.67	6.0%
4	40	47.0	2.99	6.4%	2.99	6.4%	1.13	2.4%	2.27	4.8%	2.97	6.3%
5	40	35.5	1.42	4.0%	1.56	4.4%	0.77	2.2%	1.27	3.6%	1.54	4.3%
6	40	79.4	2.87	3.6%	3.54	4.5%	2.41	3.0%	1.09	1.4%	3.60	4.5%
7	40	69.3	4.26	6.2%	5.05	7.3%	4.29	6.2%	1.37	2.0%	5.85	8.4%
8	40	106.2	3.43	3.2%	4.48	4.2%	5.30	5.0%	2.18	2.1%	6.12	5.8%

SQA-iO Progressively Motile Sperm Concentration (PMSC) Precision

PMSC			Within-Run		Between-Run		Between-Day		Between-Operator/ Lot/Instrument		Total	
Sample	**N**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
1	40	0.0	0.00	0.0%	0.00	0.0%	0.00	0.0%	0.00	0.0%	0.00	0.0%
2	40	23.2	1.11	4.8%	1.14	4.9%	0.94	4.1%	0.74	3.2%	1.38	6.0%
3	40	24.2	1.27	5.2%	1.35	5.6%	0.83	3.4%	0.90	3.7%	1.41	5.8%
4	40	42.2	2.80	6.6%	2.81	6.7%	1.16	2.8%	2.11	5.0%	2.82	6.7%
5	40	31.5	1.78	5.6%	1.86	5.9%	0.76	2.4%	1.11	3.5%	1.92	6.1%
6	40	70.3	2.64	3.8%	3.34	4.8%	2.34	3.3%	0.92	1.3%	3.40	4.8%
7	40	51.0	4.60	9.1%	5.34	10.6%	5.20	10.2%	2.51	4.9%	6.54	12.8%
8	40	93.4	3.58	3.8%	4.39	4.7%	5.32	5.7%	2.21	2.4%	6.14	6.6%

SQA-iO Normal Morphology Precision

Normal Morphology			Within-Run		Between-Run		Between-Day		Between-Operator/ Lot/Instrument		Total	
Sample	**N**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
1	40	0.0	0.00	0.0%	0.00	0.0%	0.00	0.0%	0.00	0.0%	0.00	0.0%
2	40	15.4	0.87	5.7%	0.87	5.7%	0.33	2.2%	0.78	5.1%	0.92	6.0%
3	40	11.2	1.00	9.0%	1.00	8.9%	0.25	2.2%	0.89	8.0%	0.98	8.8%
4	40	16.5	0.78	4.7%	0.83	5.0%	0.37	2.2%	0.59	3.6%	0.85	5.1%
5	40	10.2	0.58	5.7%	0.61	6.0%	0.41	4.0%	0.45	4.4%	0.66	6.5%
6	40	7.2	0.35	4.8%	0.39	5.4%	0.19	2.6%	0.26	3.6%	0.41	5.6%
7	40	3.6	0.42	11.9%	0.46	13.0%	0.39	10.7%	0.22	6.2%	0.55	15.1%
8	40	8.5	0.48	5.6%	0.53	6.3%	0.51	6.0%	0.35	4.2%	0.68	8.0%

Precision- Reproducibility (Controls Precision)

This study was designed to establish the reproducibility of the SQA-iO utilizing three levels of QwikCheck beads (controls) assayed by three different operators in three locations over a 5-day period. Six replicates of each level of QwikCheck Beads, representing varying concentration levels (High, Normal and Negative) were included, and the output parameter was sperm concentration.

For each level of control tested, the mean, SD and %CV were calculated, along with the %CV for repeatability and reproducibility (total precision).

SQA-iO Repeatability and Between-Day variation

Site	Control Level	Concentration Mean, M/ml	Repeatability		Between-Day	
			SD	%CV	SD	%CV
1	Level High L1	45.7	0.26	0.6%	0.81	1.8%
	Level Normal L2	24.0	0.04	0.2%	0.55	2.3%
	Level NEG L3	0.0	0.00	0.0%	0.00	0.0%
2	Level High L1	47.3	0.05	0.1%	0.83	1.8%
	Level Normal L2	24.8	0.03	0.1%	0.13	0.5%
	Level NEG L3	0.0	0.00	0.0%	0.00	0.0%
3	Level High L1	46.7	0.03	0.1%	0.23	0.5%
	Level Normal L2	25.6	0.01	0.0%	0.66	2.6%
	Level NEG L3	0.0	0.00	0.0%	0.00	0.0%

OVERALL

Control Level	Between-Laboratory		Between-Day		Reproducibility (Total Precision)	
	SD	%CV	SD	%CV	SD	%CV
Level High L1	0.83	1.8%	0.62	1.3%	0.73	1.6%
Level Normal L2	0.80	3.2%	0.44	1.8%	0.62	2.5%
Level Low L3	0.00	0.0%	0.00	0.0%	0.00	0.0%

Analytical sensitivity (limits of blank and detection/quantitation)

The objective of this study was to define the limit of blank (LoB), Limit of Detection (LoD) and limit of Quantitation (LoQ) of the SQA-iO system for sperm concentration.

Following the guidance of CLSI EP17-A2, the study included a BLANK (seminal plasma) and a LOW-LEVEL sample of sperm concentration. The samples were assayed 12 times on each of five SQA-iO devices (60 tests per level).

The data demonstrated the following:

Limit of Blank (LoB) = 0 M/mL
Limit of Detection (LoD) = 1.73 M/mL
Limit of Quantitation (LoQ) = 5.96 M/mL

Linearity (measurement range)

The dynamic range and linearity of the SQA-iO instrument (concentration, M/mL) were established by using three SQA-iO devices and one SQA-V reference system. Semen samples were prepared at nine semen concentration intervals ranging from low to high level (less than 2 to 400 M/mL). The test was performed in three SQA-iO devices per concentration level, and results were compared to the average of

the triplicate results of the SQA-V analyzer.

It was demonstrated that the SQA-iO linear regression coefficients "R" exceeded 0.9.

Interference

The interference study was based on the CLSI EP07, 3rd ed. guidelines, i.e., each contaminant was added as 1/20 part of the sample resulting in a 5%/95% ratio. The spiked and control samples were tested by the SQA-iO at two sperm concentration levels defined as "low " (15-60 M/mL) and "high" (100–200 M/mL), and data were reported for concentration, motility, MSC, PMSC, and morphology. The data demonstrated no significant differences between spiked and controls at both levels and across all reported parameters.

Sample Stability

This study was performed to demonstrate the stability of semen motility parameters. It is a known fact that sperm motility decreases over time, and therefore MES proposes, in its SQA-iO labeling, to follow WHO 4th, 5th and 6th guidelines that state that semen should be tested within 1 hour of collection. In this study, the motility parameters of % motility, MSC and PMSC (the presumptive "worst-case" parameters for sample stability) were assessed at various time intervals, and results were compared to their initial (T0) results following the scheme below:

T0 - within 1 hour of collection but after sample liquefaction

T1 - 2 hours post collection

T2 - 3 hours post collection

T3 - 4 hours post collection

The study results indicate that motility parameters are reasonably stable at 2 hours post collection, but individual samples can vary widely. Additionally, the study results support the WHO recommendations to perform semen analysis within 1 hour of collection.

Electrical Safety Tests

Electrical safety tests and EMC tests on the SQA-iO Sperm Quality Analyzer were performed according to the following standards:

- IEC 61010-1 Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirements
- IEC 61010-2-101 Safety requirements for electrical equipment for measurement, control and laboratory use Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
- EMC: IEC 60601-1-2 General requirements for basic safety and essential performance related with electromagnetic compatibility of Medical Devices

It was demonstrated that the SQA-iO device has successfully passed all the tests specified by the above standards, according to all applicable standard requirements. There were no deviations or modifications made to the tested version of the SQA-iO device in order to pass any of the electrical safety and EMC tests.

Environmental Tests

The environmental test evaluating the transportation and environmental stress impact on the SQA-iO was performed according to ASTM 4332-14 and ASTM D4169-16. The tests included evaluating the SQA-iO in extreme climatic and transportation conditions, including desert conditions (high temperatures with low humidity), extreme cold (low temperatures), tropical conditions (high temperatures and high humidity), free fall (drop), bump, random vibrations, and low air pressure conditions expected in its application environment and during transportation.

It was demonstrated that the SQA-iO withstands the transportation and environmental conditions in compliance with the standard requirements as no deterioration in the functional performance of the tested SQA-iO was observed following the environmental challenges.

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

Method Comparison Study

Method comparison data were based on comparative testing of 165 matched native semen samples that were assayed according to WHO 6th criteria by the SQA-iO (on-test) and the SQA-V (reference) methods across three sites. At each site, one SQA-iO device and one SQA-V device were used.

The SQA-iO operators (n = 12 across all sites) were laboratory technicians or professionals who are familiar with semen analysis. In parallel, an expert operator assayed the same sample in duplicate on the SQA-V predicate, and the means of the SQA-V results were used as the comparator results.

The data were analyzed by Passing-Bablok regression (SQA-V on x-axis), and the y-intercepts, slopes, and correlation coefficients, along with the 95% confidence intervals, are shown in the table, below.

SQA-iO vs. SQA-V (n = 165)

Parameter	Intercept	CI	Slope	CI	Correlation	CI
CONCENTRATION, M/mL	-1.5	-2.0 to -0.7	1.0	1.0 to 1.0	1.0	0.98 to 0.99
MOTILITY, %	-3.0	-3.1 to -1.7	1.0	1.0 to 1.0	1.0	0.95 to 0.97
PROGRESSIVE MOTILITY, %	-0.8	-1.0 to 0.0	0.9	0.9 to 1.0	1.0	0.97 to 0.98
RAPIDLY PROGRESSIVE, %	0.1	0.0 to 0.3	1.0	0.9 to 1.0	0.9	0.90 to 0.94
SLOWLY PROGRESSIVE, %	-0.8	-1.0 to 0.0	1.0	0.9 to 1.0	0.9	0.86 to 0.93
NON-PROGRESSIVE, %	-1.9	-3.0 to -1.0	1.2	1.0 to 1.3	0.8	0.71 to 0.83
IMMOTILE, %	3.0	1.0 to 5.0	1.0	1.0 to 1.0	1.0	0.95 to 0.97
MSC, M/mL	-0.9	-1.7 to -0.6	1.0	1.0 to 1.0	1.0	0.98 to 0.99
PMSC, M/mL	-0.4	-0.7 to -0.3	1.0	0.9 to 1.0	1.0	0.99 to 1.00
RAPID PMSC, M/mL	0.0	-0.1 to 0.0	1.0	1.0 to 1.0	1.0	0.96 to 0.98
SLOW PMSC, M/mL	-0.1	-0.4 to -0.1	1.0	0.9 to 1.0	1.0	0.98 to 0.99
MORPHOLOGY, % (n = 155)	0.0	0.0 to 0.1	1.0	0.9 to 1.0	1.0	0.96 to 0.98
FSC, M/mL (n = 155)	-0.1	-0.1 to 0.0	0.9	0.9 to 1.0	1.0	0.97 to 0.99

The data demonstrate slopes between 0.9 and 1.2, Y-intercepts near zero, and a correlation coefficients. ("r") ≥0.8.

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

The SQA-iO testing confirms that the device can be used according to its intended use and in an equivalent manner to the predicate device. 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.