510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K243114

B Applicant

Medical Electronic Systems Ltd.

C Proprietary and Established Names

SQA-iOw Sperm Quality Analyzer

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
POV	Class II	21 CFR 864.5220 - Automated Differential Cell Counter	HE - Hematology

II Submission/Device Overview:

A Purpose for Submission:

This submission is a Dual 510(k) and CLIA Waiver by Application (Dual Submission) tracked as K243114 and CW240024. CW240024 is for granting the CLIA Waiver by Application.

B Measurand:

Measured parameters:

- Sperm Concentration, M/mL
- Motile Sperm Concentration (MSC), M/mL
- Progressively Motile Sperm Concentration (PMSC), M/mL
- Normal Forms (Normal Morphology), %

Calculated parameters:

- Total Motility (PR + NP), %
- Progressive Motility (PR), %

- Non-Progressive Motility (NP), %
- Immotile (IM), %

C Type of Test:

Analysis of semen parameters

III Intended Use/Indications for Use:

A Intended Use(s):
See Indications for Use below.

B Indication(s) for Use:
The SQA-iOw 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.

C Special Conditions for Use Statement(s):
Rx - For Prescription Use Only

The SQA-iOw Sperm Quality Analyzer is intended to be used by operators with a minimum of an earned high school diploma or equivalent.

IV Device/System Characteristics:

A Device Description:

The SQA-iOw Sperm Quality Analyzer is a PC-based automated device that tests human semen samples, using a cloud-based application for device control, data analysis, and data storage. The SQA-iOw utilizes software to both perform analysis of semen parameters and to present those results on the user interface. It provides directly measured and calculated measurements for total

sperm concentration, percent motility, percent immotile, percent progressive motility, percent non-progressive motility, percent normal forms, motile sperm concentration, progressive motile sperm concentration, and functional sperm concentration.

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

The cleaning kit includes the following components:

- Long cleaning brush
- Fibrous material cleaning paddles (single use)
- Sponge-tipped drying paddles (single use)
- Cleaning fluid (50% Ethanol, 49.5% Distilled Water, 0.5% Tween 20) (single drop dispenser)

B Principle of Operation:

After collection and preparation, 0.6 mL of semen sample is manually 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 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-iOw 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.

C Instrument Description Information:

1. Instrument Name:

   SQA-iOw Sperm Quality Analyzer

2. Specimen Identification:

   Specimen identification is manually entered in the 'Test Patient' field of the software, prior to sample analysis.

3. Specimen Sampling and Handling:

   A minimum of 0.6 mL of semen is required. Sample should be self-collected without using lubricants or other creams. The sample should be maintained at room temperature (do not heat or refrigerate), tested fresh (within 1 hour of collection) and be fully liquified.

4. Calibration:

   Internal electronic Self-Test/Auto-Calibration runs at start-up. Reference values verified prior to each test.

5. Quality Control:

QwikCheck Beads (cleared under K041600) are used for performing quality control. The three levels should be analyzed every 24 hours or prior to sample analysis.

V Substantial Equivalence Information:

A Predicate Device Name(s):
SQA V, Sperm Quality Analyzer

B Predicate 510(k) Number(s):
K021746

C Comparison with Predicate(s):

Device & Predicate Device(s):	K243114	K021746
Device Trade Name	SQA-iOw Sperm Quality Analyzer	SQA V, Sperm Quality Analyzer
General Device Characteristic Similarities		
Intended Use/Indications For Use	The SQA-iOw 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	The SQA V is a point-of-care, easy-to-use, electro-optical device with on-screen visualization and image freezing capabilities for semen analysis. The SQA V provides direct and calculated measurements for: • Total sperm concentration (TSC, millions/ml) • Percent motility (%MOT) and % progressive motility (%PMOT) • % Normal morphology (%MORPH) • Motile sperm concentration (MSC, millions/mL) and progressive

	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.	MSC (PMSC) • Functional sperm concentration (FSC, millions/mL)
Sample Type	Human Semen	Same
Testing Capillary	SQA-V testing capillary	Same
External Controls	QwikCheck Beads (cleared under K041600)	Same
Liquefication	QwikCheck Liquefaction vials	Same
General Device Characteristic Differences		
WHO Manual for the Laboratory Examination and Processing of Human Semen	6th edition	4th and 5th edition
Technology	Desk-top unit consists of a light source and optical sensors, connected to a PC that	Desk-top unit consists of a light source, optical sensors, built-in video microscopy and an

	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.	internal computer containing algorithms for the assessment of semen parameters.
Sample Visualization	None	Contains built-in video microscopy system allowing for Sample visualization report.

VI Standards/Guidance Documents Referenced:

- IEC 61010-1-Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements, Edition 3.1 (Consolidated Version 2017)
- IEC 61010-1-2-Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests, Edition 4.1 (2020)
- ASTM D4169-22 Standard Practice for Performance Testing of Shipping Containers and Systems
- ASTM D4332-22 Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing
- CLSI EP05-A3, Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision:

a) **Repeatability**: The study was conducted at two sites with six operators using six instruments. Nine native semen samples were tested in duplicate. The samples were run post-liquefication at four timepoints (0, 10 minutes, 20 minutes, 30 minutes). Five lots of capillaries were used. Within-run and between-operator were evaluated, and the mean, standard deviation (SD), and coefficient of variation (%CV) are provided for each parameter. All samples were evaluated against all applicable acceptance criteria and met all acceptance criteria requirements.

Sperm Concentration (M/mL)

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%
8	24	15.81	1.316	8.3%	1.807	11.4%	2.236	14.1%
9	24	14.70	0.740	5.0%	1.775	12.1%	1.923	13.1%

Motile Sperm Concentration (MSC, M/mL)

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	N/A	0.000	N/A	0.000	N/A
7	24	1.60	0.000	N/A	0.000	N/A	0.000	N/A
8	24	9.42	0.632	N/A	1.219	N/A	1.373	N/A
9	24	4.32	0.627	N/A	1.684	N/A	1.797	N/A

Progressively Motile Sperm Concentration (PMSC, M/mL)

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	N/A	0.014	N/A	0.043	N/A
7	24	0.09	0.245	N/A	0.088	N/A	0.260	N/A
8	24	6.80	0.535	N/A	0.652	N/A	0.844	N/A
9	24	2.97	0.538	N/A	1.083	N/A	1.209	N/A

Normal Forms (Morphology, %)

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	N/A	0.204	N/A	0.289	N/A
7	24	0.33	0.764	N/A	0.289	N/A	0.816	N/A
8	24	8.38	0.736	8.8%	0.500	6.0%	0.890	10.6%
9	24	3.50	0.913	N/A	0.722	N/A	1.164	N/A

Total Motility (%)

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%

Progressive Motility (%)

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	N/A	0.556	N/A	1.243	N/A
7	24	1.75	1.029	N/A	0.514	N/A	1.150	N/A
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%

Non-Progressive (%)

Sample #	N	Mean	Repeatability		Between-operator		Total	
			SD	%CV	SD	%CV	SD	%CV
1	24	8.24	2.504	N/A	1.252	N/A	2.800	N/A
2	24	7.34	2.822	N/A	1.411	N/A	3.155	N/A
3	24	9.30	2.930	N/A	1.465	N/A	3.276	N/A
4	24	5.13	3.520	N/A	1.760	N/A	3.935	N/A
5	24	7.93	2.713	N/A	1.357	N/A	3.034	N/A
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	N/A	1.425	N/A	3.187	N/A

Immotile (%)

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%

b) **Reproducibility**: The study was conducted at three sites with three operators per site using three instruments for three days. Three levels of QwikCheck control beads (Level 1, Level 2, Negative) were tested in duplicate per day with three lots of capillaries. Within-run, between-operator, between-day, and between-site were evaluated. The mean, standard deviation (SD), and coefficient of variation (%CV) are provided for all sites combined for each concentration level. All samples were evaluated against all applicable acceptance criteria and met all acceptance criteria requirements.

Sample	N	Mean	Repeatability (Within-run)		Between-day		Between-run/ operator		Between site/ instrument		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Level 1	90	47.8	0.12	0.24%	0.40	0.83%	0.35	0.74%	0.69	1.45%	0.88	1.84%
Level 2	90	24.9	0.06	0.23%	0.57	2.28%	0.45	1.83%	0.68	2.73%	1.00	4.01%
Negative	90	0.0	0.00	0.00%	0.00	0.00%	0.00	0.00%	0.00	0.00%	0.00	0.00%

2. Linearity:

Please refer to K220828.

3. Analytical Specificity/Interference:

Please refer to K220828.

4. Assay Reportable Range:

The measuring range for Sperm concentration was determined from the Linearity and the Limit of Quantitation study results.

Parameter	**Range**
Sperm Concentration (M/mL)	<6–400
Total Motility (%)	0–100
Progressive Motility (%)	0–100
Non-Progressive (%)	0–100
Immotile (%)	0–100
Normal Forms (%)	0–30
Motile Sperm Concentration (M/ml)	0.2–250
Progressively Motile Sperm Concentration (M/mL)	0–200

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

Please refer to K220828.

6. Detection Limit:

Please refer to K220828.

7. Assay Cut-Off:

Not applicable

8. Accuracy (Instrument):

   See Method Comparison study section.

9. Carry-Over:

   Not Applicable

B Comparison Studies:

1. Method Comparison: The study was conducted across three U.S. sites with nine untrained operators to evaluate the performance of the SQA-iOw system compared to the comparative method, SQA V system. A total of 380 native semen samples were included in the study. At each site, one SQA-iOw device and one SQA V device were used. The data were analyzed with the Passing-Bablok regression and the results for combined sites are shown in the table below. The results met the acceptance criteria.

Parameter	**N**	**Range**	**Intercept (95% CI)**	**Slope (95% CI)**
Sperm Concentration, M/mL	380	6–272.5	0.05 (-0.18, 0.27)	0.98 (0.97, 0.98)
Motility, %	380	0–100	1.94 (1.13, 2.77)	0.94 (0.92, 0.96)
Progressive Motility, %	380	0–88	-0.26 (-0.79, 0.00)	0.94 (0.93, 0.96)
Non-Progressive, %	380	1–30	-0.33 (-0.63, 0.00)	1.33 (1.25, 1.38)
Immotile, %	380	0–99	3.37 (2.47, 4.35)	0.95 (0.93, 0.97)
Morphology, %	380	0–22	-1.00 (-1.00, 0.00)	1.00 (0.90, 1.00)
MSC, M/mL	380	0.2–151.7	0.27 (0.05, 0.46)	0.95 (0.93, 0.95)
PMSC, M/mL	380	0–139.5	-0.17 (-0.31, 0.00)	0.92 (0.91, 0.93)

Agreement analysis (positive percent agreement (PPA), negative percent agreement (NPA))

Parameter	**N**	**PPA (95%CI)**	**NPA (95%CI)**
Sperm Concentration, M/mL	398	98.5% (96.6%, 994.4%)	96.8% (89.1%, 99.1%)
Morphology, %	373	95.1% (92%, 97.1%)	96.6% (90.3%, 98.8%)
MSC, M/mL	398	98.1% (95.9%,99.1%)	90% (81.5%, 94.8%)

Parameter	N	PPA (95%CI)	NPA (95%CI)
PMSC, M/mL	381	96.9% (94.4%, 98.3%)	96.7% (88.6%, 99.1%)
Motility, %	398	97.4% (94.6%, 98.7%),	95.5% (90.5%, 97.9%)
Progressive Motility, %	379	94.9% (91.7%, 97.0%)	98.0% (93.1%, 99.5%)
Non-Progressive, %	379	99.5% (98.1%, 99.9%)	0.0% (0.0%, 65.8%)
Immotile, %	379	99.7% (98.5%, 100%)	46.6% (24.8%, 69.9%)

2. Matrix Comparison:

   Not applicable

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable

2. Clinical Specificity:

   Not applicable

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Not applicable

D Clinical Cut-Off:

Not applicable

E Expected Values/Reference Range:

Please refer to K220828.

F Other Supportive Instrument Performance Characteristics Data:

Not applicable

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.