510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY

I Background Information:

A 510(k) Number

K241628

B Applicant

Medical Electronic Systems Ltd.

C Proprietary and Established Names

YO Home Sperm Test

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:

Clearance of a new device

B Type of Test:

Quantitative analysis of the following semen parameters:
Total Sperm Concentration / Sperm Concentration, M/mL
Total Motile / Motility (PR + Non Progressive [NP]), %
Progressive Motility (PR), % (combines Rapidly and Slowly Progressive, %)
Motile Sperm Concentration (MSC), M/mL
Progressively Motile Sperm Concentration (PMSC), M/mL (combines Rapidly and Slowly Motile Sperm Concentration, M/mL)

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The YO Sperm Test (YO 3.0) is a smartphone-based home test for semen analysis performed by lay users.

The parameters reported by the YO Home Sperm Test (YO 3.0) are:

1. Total Sperm Concentration / Sperm Concentration, M/mL
2. Total Motile / Motility (PR + Non Progressive [NP]), %
3. Progressive Motility (PR), % (combines Rapidly and Slowly Progressive, %)
4. Motile Sperm Concentration (MSC), M/mL
5. Progressively Motile Sperm Concentration (PMSC), M/mL (combines Rapidly and Slowly Motile Sperm Concentration, M/mL)

The YO Home Sperm Test (YO 3.0) does not provide a comprehensive evaluation of a male's fertility status and is intended for in vitro, over the counter only.

C Special Conditions for Use Statement(s):

OTC - Over The Counter

IV Device/System Characteristics:

A Device Description:

The YO Home Sperm Test (YO 3.0) is a smartphone-based, over-the-counter, home test for semen analysis performed by lay users that provides a quantitative analysis of total sperm concentration, total motile/motility, progressive motility, motile sperm concentration (MSC) and progressively motile sperm concentration (PMSC). The YO Home Sperm Test (YO 3.0) utilizes proprietary algorithms to both conduct semen analysis and present and store the results and videos on the user's smartphone and in the cloud. The YO application (app) is downloaded onto the user's own smartphone (iPhone/Android) and is controlled by the user through a proprietary graphical interface (GUI). The GUI guides the user through the process step by step on the App's screen and operates the YO device.

The YO Home Sperm Test kit provides the supplies necessary to test up to six semen samples and contains:

- Plastic cups for collecting the semen sample
- Fixed coverslip slides
- Vials containing 5 mg chymotrypsin liquefaction media
- Disposable plastic pipettes for sample aspiration and delivery to the fixed coverslip slide
- YO Device
- USB cable for connecting the YO device to the user's smartphone/PC
- Indications for Use

B Principle of Operation:

The plastic YO device contains a fixed coverslip slide insertion channel, magnification lens, lens holder, WiFi camera and an LED that lights up the optical path. A specimen-filled slide is inserted into the OTC device unit and illuminated by the light source. The image is magnified by a magnification lens in the YO device and projected to the image sensors (YO camera). The camera transmits the video to the smartphone. The YO software captures a video in HD (high definition) mode and implements a unique software algorithm to identify sperm and analyze the light fluctuations resulting from sperm movement to report semen values. The algorithm recognizes when the YO autofocus function has the best image and then defines the optimal area of the video for analysis. MSC/PMSC are measured by capturing a video of sperm cells in high definition (HD) mode, and analyzing the moving and total spermatozoa, expressed in millions per milliliter (M/mL). Sperm concentration is calculated by counting the objects from the same sperm video and classifying them as sperm cells.

C Instrument Description Information:

1. Instrument Name:

   YO Home Sperm Test

2. Specimen Identification:

   Specimen identification is not required because the YO Home Sperm Test is intended for a single user at home.

3. Specimen Sampling and Handling:

   The users are instructed to wash their hands with soap and water before and after handling their semen sample or test components. If the user is running the test for someone else, the user will wear exam gloves. When instructed by the YO app, the user collects the sample directly into the sample container provided in the YO kit. The sample should be placed at room temperature. Once the user places the liquefaction powder into the sample as directed in the application, the user should wait ten minutes before testing as instructed. The App instructs the user to not wait longer than one hour from collection to test the sample.

4. Calibration:

   Not applicable.

5. Quality Control:

   Internal controls are performed automatically and internally. The software checks that the video signal is stabilized and running smoothly for analysis and that the video is not black or blank.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Sqa V, Sperm Quality Analyzer, YO Home Sperm Test

B Predicate 510(k) Number(s):
K021746, K161493

C Comparison with Predicate(s):

Device & Predicate Device(s):	K241628	K161493	K021746
Device Trade Name	YO Home Sperm Test	YO Home Sperm Test	SQAV, Sperm Quality Analyzer
General Device Characteristic Similarities			
Intended Use/Indications For Use	The YO Home Sperm Test (YO 3.0) is a smartphone-based home test for semen analysis performed by lay users. The parameters reported by the YO Home Sperm Test (YO 3.0) are: 1. Total Sperm Concentration/Sperm Concentration, M/mL 2. Total Motile/Motility (PR + Non Progressive [NP], % 3. Progressive Motility (PR), % (combines Rapidly and Slowly Progressive, %) 4. Motile Sperm Concentration (MSC), M/mL 5. Progressively Motile Sperm Concentration (PMSC), M/mL (combines Rapidly and Slowly Motile Sperm Concentration,	The YO Home Sperm Test is a smartphone-based home test which provides a qualitative assessment of motile sperm concentration (MSC) in human semen. MSC is one aspect of a male semen examination. The YO Home Sperm Test does not provide a comprehensive evaluation of a male's fertility status and is intended for over-the-counter, in vitro use only.	The SQAV is a point-of-care, easy-to-use, electro-optical device with on-screen visualization and image freezing capabilities for semen analysis. The SQQ 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 MSC (PMSC) • Functional sperm concentration

	M/mL) The YO Home Sperm Test (YO 3.0) does not provide a comprehensive evaluation of a male's fertility status and is intended for in vitro, over-the-counter (Home Use) use only.		(FSC, millions/mL)
Intended User	Lay Users	Same	Healthcare Professionals (trained lab technicians)
WHO compliance	WHO 6th	WHO 5th	WHO 5th and WHO 6th
Sample Type	Human semen	Same	Same
Sample delivery method	YO Fixed Cover Slip Slide which is inserted into the YO device	Same	SQA-V testing capillary which is inserted into the SQA-V device
Semen parameters	• Total Sperm Concentration/Sperm Concentration, M/mL • Percent Motility/Total Motile (PR+NP), % • Motile Sperm Concentration (MSC), M/mL • Progressive Motility (PR), % (combines Rapidly and Slowly Progressive, %) • Progressively Motile Sperm Concentration (PMSC), M/mL (combines Rapidly and Slowly Motile Sperm Concentration, M/mL)	• Motile Sperm Concentration (MSC), millions/mL above and below the 6M/mL cut-off for normal/abnormal. Results are presented as LOW or Moderate/Normal Range	• Sperm concentration/Total Sperm Concentration, M/mL • Percent Motility/Total Motile (PR+NP), % • Motile Sperm Concentration (MSC), M/mL The SQA-V also reports other parameters.
Test Type	Quantitative	Qualitative	Quantitative
General Device Characteristic Differences			
Technology	Desktop unit consists of	Magnification "Clip"	Desktop unit consists of

	a light source, and image sensors (camera), wirelessly connected to a smartphone, onto which the cloud-based software is downloaded. The software is used to capture and analyze magnified sperm videos using a proprietary algorithm to produce results. A specimen filled slide is inserted into the OTC device unit and illuminated by the light source. The image is magnified by a magnification lens in the YO device and projected to the image sensors (YO camera). The camera transmits the video to a smartphone.	which slides over the top of the Smartphone. Software downloaded onto the phone is used to capture and analyze magnified sperm videos using a proprietary algorithm to produce results. A specimen-filled slide is inserted into the "Clip" and illuminated by the smartphone's light source. In addition, the "Clip" utilizes the smartphone's lens and image sensors (camera) to assess semen parameters. The image is magnified by the magnification lens in the "Clip", and using mirrors projected back to the smartphone's lens and to the smartphone's image sensors (camera).	a light source, optical sensors (electro-optical processing, conversion of light fluctuations to analog signals), built-in video microscopy and an internal computer containing algorithms for the assessment of semen parameters. A specimen-filled capillary is inserted into the desktop unit and illuminated by the light source.
Connection Technology	Wireless to smartphone/USB cable to power the YO device	Physical connection to a smartphone with the use of a clip that slides over the top of the smartphone	RS32 cable to PC
Software	Cloud-based software	On-premise software	On-premise software

VI Standards/Guidance Documents Referenced:

- CLSI EP05-A3: Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Third Edition
- CLSI EP07-3rd Edition: Interference Testing in Clinical Chemistry; Approved Guideline – Third Edition
- CLSI EP17-A2: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition
- CLSI EP06: Evaluation of Linearity of Quantitative Measurement Procedures, 2nd Edition
- ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems
- IEC 61010-1 Edition 3.1 2017-01 Safety Requirements for Electrical Equipment For Measurement, Control, And Laboratory Use – Part 1: General Requirements

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Repeatability
Seventy-eight lay users at three US sites tested their own samples in triplicate using multiple devices and three different slide lots (one per site). Parameters reported were sperm concentration, motile sperm concentration, progressively motile sperm concentration, motility and progressive motility. The Standard deviations (SDs) and percent coefficients of variation (%CVs) were calculated for each sample. The samples spanned the sperm concentration range of 2–150 M/mL. The results from all samples demonstrated acceptable repeatability of the device used by lay users.

Reproducibility
Sixteen native semen samples, representing different levels of sperm concentration, motile sperm concentration and progressively motile sperm concentration were assayed in duplicate on three devices at three sites over four timepoints. Due to limited stability of semen samples, each "day" is represented by different times of day with testing at four different timepoints, resulting in 24 replicates per sample for each of the five parameters. Standard deviations (SDs) and percent coefficients of variation (%CVs) were calculated for each sample. The results met the pre-defined acceptance criteria.

CONCENTRATION, M/ml								
Sample #	**N (total replicates)**	**Mean, M/mL**	**Within-run**		**Between-run**		**Between-operator/lot/instrument**	
			SD	**%CV**	**SD**	**%CV**	**SD**	**%CV**
Sample 1	24	36.2	2.6	7.3%	1.6	4.4%	2.9	8.1%
Sample 2	24	36.7	1.9	5.2%	1.5	4.1%	2.2	6.0%
Sample 3	24	65.5	3.2	4.9%	3.0	4.6%	3.9	6.0%
Sample 4	24	103.5	6.9	6.5%	7.7	7.4%	11.6	11.2%
Sample 5	24	46.6	2.9	6.3%	2.1	4.4%	2.9	6.3%
Sample 6	24	7.8	1.2	15.4	1.7	21.8%	1.8	23.1%
Sample 7	24	42.9	3.4	8.1%	3.0	7.0%	4.2	9.7%
Sample 8	24	6.0	0.6	10.0%	1.5	25.0	1.2	20.0%
Sample 9	24	38.8	2.4	6.2%	2.1	5.6%	3.0	7.8%
Sample 10	24	9.8	1.2	12.2%	1.7	17.3%	1.5	15.3%
Sample 11	24	7.1	1.7	23.9%	1.4	19.7%	1.9	26.8%
Sample 12	24	104.2	17.7	17.1%	6.7	6.3%	16.2	15.6%
Sample 13	24	71.2	9.1	12.5%	3.8	5.3%	10.0	14.1%
Sample 14	24	65.7	7.5	11.3%	4.8	7.4%	7.6	11.6%
Sample 15	24	4.9	0.7	14.3%	0.6	12.2	0.9	18.4%
Sample 16	24	14.8	1.1	7.4%	1.8	12.4%	1.6	10.5%

MSC, M/ml								
Sample #	N (total replicates)	Mean, M/mL	Within-run		Between-run		Between-operator/lot/instrument	
			SD	%CV	SD	%CV	SD	%CV
Sample 1	24	28.6	2.4	8.4%	0.9	3.3%	2.6	9.0%
Sample 2	24	32.7	1.8	5.4%	1.4	4.2%	2.1	6.4%
Sample 3	24	57.9	2.9	10.0%	2.6	4.5%	3.5	6.0%
Sample 4	24	74.7	2.3	3.1%	5.5	7.6%	4.5	6.0%
Sample 5	24	39.8	4.2	10.5%	1.9	4.8%	3.4	8.6%
Sample 6	24	5.4	0.7	N/A	1.1	N/A	1.0	N/A
Sample 7	24	38.0	3.1	8.1%	2.9	7.6%	3.8	10.0%
Sample 8	24	3.6	0.2	N/A	0.9	N/A	0.4	N/A
Sample 9	24	34.0	2.1	6.3%	2.0	5.9%	2.6	7.5%
Sample 10	24	7.4	0.9	12.2%	1.5	20.3%	1.3	17.6%
Sample 11	24	4.8	1.0	N/A	0.6	N/A	0.9	N/A
Sample 12	24	72.3	7.2	9.9%	2.8	3.9%	6.6	9.2%
Sample 13	24	60.5	7.7	12.7%	3.3	5.5%	7.3	12.1%
Sample 14	24	47.1	5.2	11.1%	6.3	13.5%	4.8	10.3%
Sample 15	24	4.0	0.6	N/A	0.6	N/A	0.8	N/A
Sample 16	24	10.4	1.1	10.7%	0.8	7.8%	1.2	11.5%
PMSC, M/ml								
Sample #	N (total replicates)	Mean, M/mL	Within-run		Between-run		Between-operator/lot/instrument	
			SD	%CV	SD	%CV	SD	%CV
Sample 1	24	26.4	3.3	12.7%	1.4	5.3%	3.3	12.4%
Sample 2	24	31.1	1.7	5.4%	1.3	4.3%	2.0	6.4%
Sample 3	24	55.0	2.8	10.0%	2.4	0.0%	3.3	6.1%
Sample 4	24	70.2	3.0	4.3%	6.5	9.4%	4.6	6.6%
Sample 5	24	37.8	4.0	10.5%	1.8	4.8%	3.3	8.6%
Sample 6	24	2.4	0.8	N/A	0.8	N/A	1.0	N/A
Sample 7	24	36.1	2.9	8.1%	2.7	7.6%	3.6	10.0%
Sample 8	24	0.7	0.3	N/A	0.9	N/A	0.4	N/A
Sample 9	24	32.3	2.0	6.3%	1.9	5.9%	2.4	7.5%
Sample 10	24	4.5	0.9	N/A	1.2	N/A	1.1	N/A
Sample 11	24	2.0	0.7	N/A	0.5	N/A	0.7	N/A
Sample 12	24	69.0	7.5	10.9%	2.3	3.3%	6.2	9.0%
Sample 13	24	57.2	6.9	12.0%	3.1	5.3%	6.6	11.6%
Sample 14	24	43.6	5.9	13.6%	7.4	17.1%	5.7	13.1%
Sample 15	24	1.8	0.7	N/A	0.7	N/A	0.7	N/A
Sample 16	24	6.4	1.5	23.4%	1.3	20.3%	1.6	25.0%

MOTILITY, %								
Sample #	N (total replicates)	Mean, M/mL	Within-run		Between-run		Between-operator/lot/instrument	
			SD	%CV	SD	%CV	SD	%CV
Sample 1	24	79.3	6.7	8.5%	4.2	5.3%	6.7	8.4%
Sample 2	24	89.2	1.3	1.4%	1.2	1.4%	1.8	2.1%
Sample 3	24	88.4	1.8	2.0%	2.6	2.9%	2.0	2.3%
Sample 4	24	72.7	3.7	5.1%	6.7	9.2%	5.0	6.9%
Sample 5	24	85.2	5.3	6.2%	1.9	2.2%	4.9	5.7%
Sample 6	24	69.4	10.0	14.4%	5.3	7.6%	11.0	15.9%
Sample 7	24	88.8	1.8	2.0%	1.2	1.4%	2.5	2.8%
Sample 8	24	61.4	6.4	10.4%	11.2	18.2%	10.7	17.4%
Sample 9	24	87.7	2.9	3.3%	2.3	2.6%	3.2	3.6%
Sample 10	24	74.9	5.1	6.8%	5.4	7.2%	6.8	9.1%
Sample 11	24	69.4	7.4	10.7%	6.4	9.2%	8.6	12.4%
Sample 12	24	70.3	6.0	8.5%	3.3	4.8%	6.4	9.2%
Sample 13	24	85.3	4.0	4.7%	2.5	3.0%	4.7	5.6%
Sample 14	24	71.6	3.2	4.5%	6.6	9.3%	5.1	7.1%
Sample 15	24	80.1	4.6	5.7%	5.2	6.5%	6.5	8.1%
Sample 16	24	71.2	6.2	8.7%	8.4	11.8%	7.4	10.4%

PROGRESSIVE MOTILITY, %								
Sample #	N (total replicates)	Mean, M/mL	Within-run		Between-run		Between-operator/lot/instrument	
			SD	%CV	SD	%CV	SD	%CV
Sample 1	24	73.1	9.3	12.7%	5.7	7.7%	9.1	12.5%
Sample 2	24	84.7	1.2	1.4%	1.2	1.4%	1.7	2.1%
Sample 3	24	84.0	1.8	2.1%	2.5	3.0%	1.9	2.3%
Sample 4	24	68.3	4.2	6.1%	7.5	11.0%	5.3	7.7%
Sample 5	24	81.0	5.1	6.3%	1.8	2.2%	4.7	5.8%
Sample 6	24	30.9	11.5	37.2%	8.1	26.2%	13.0	42.1%
Sample 7	24	84.4	1.7	2.0%	1.2	1.4%	2.4	2.8%
Sample 8	24	9.8	5.9	N/A	12.9	N/A	6.9	N/A
Sample 9	24	83.3	2.7	3.3%	2.2	2.6%	3.0	3.7%
Sample 10	24	45.4	7.3	16.1%	4.8	10.6%	8.2	18.1%
Sample 11	24	28.6	8.0	28.0%	5.0	17.5%	9.7	33.9%
Sample 12	24	66.9	5.3	7.9%	2.6	4.0%	5.5	8.3%
Sample 13	24	80.7	3.3	4.1%	2.7	3.4%	4.2	5.1%
Sample 14	24	66.3	4.5	6.9%	8.6	13.2%	7.0	10.5%
Sample 15	24	34.6	11.4	32.9%	11.6	33.5%	10.4	30.1%
Sample 16	24	44.2	10.0	22.6%	11.7	26.5%	11.3	25.6%

2. Linearity:

Linearity of the YO Home Sperm Test (YO 3.0) was evaluated for the sperm concentration using three YO 3.0 devices with one replicate per device. Native semen samples were prepared by pooling native samples from ten donors and concentrating sperm via centrifugation and removal of the supernatant. The sperm pellet was aliquoted into seminal plasma and the low-level concentration sample was confirmed by testing with the SQA-V comparator. The sperm concentration was demonstrated to be linear from 2–150 M/mL.

3. Analytical Specificity/Interference:

The potential interference of various substances on YO 3 were evaluated by using two sperm concentration levels (20–60 M/mL and 60–100 M/mL). The parameters of sperm concentration, motile sperm concentration and progressively motile sperm concentration were evaluated. The following 11 interfering substances were tested in the study at the recommended level: yeast, E. coli, Vitamin B12, urine, saliva, red blood cells (RBCs), white blood cells (WBCs), testosterone, β-estradiol, D-norgestrel and agglutinates. Samples were compared to a native control sample composed of seminal plasma. Results showed that all tested interfering substances met the acceptance criteria, so no significant interference was caused by the tested substances at the evaluated level.

4. Accuracy (Instrument)

Method Comparison

The method comparison study was conducted at three U.S. sites and included 309 native semen samples with approximately 100 semen samples per site, assayed in singleton and in a blinded fashion by the intended users. The intended users analyzed their own samples. In addition, some female intended users were enrolled to test donor semen samples. In parallel, trained operators tested the sample on the SQA-V comparator device. The data were analyzed by the Passing-Bablok regression, and the results are shown in the table below. The results met the pre-defined acceptance criteria.

Parameter	N	Range	Slope (95% CI)	Intercept (95% CI)	Correlation (95% CI)
Concentration, M/mL	309	2.0 to 150.0	0.86 (0.82, 0.91)	2.29 (1.29, 3.25)	0.93 (0.92, 0.95)
Motility, %	309	0.0 to 90.0	1.05 (1.00, 1.11)	0.0 (0.00, 3.00)	0.90 (0.88, 0.92)
Progressive motility, %	309	0.0 to 86.0	1.24 (1.16, 1.31)	-0.47 (-2.78, 0.00)	0.88 (0.85, 0.90)
MSC, M/mL	309	0.0 to 94.5	0.92 (0.88, 0.95)	1.84 (1.50, 2.20)	0.94 (0.93, 0.95)
PMSC, M/mL	309	0.0 to 84.0	1.03 (0.98, 1.07)	-0.04 (-0.44, 0.00)	0.94 (0.92, 0.95)

B Expected Values/Reference Range:

The lower limit of the reference range for parameters Total Sperm Concentration, Total Motility (%), and Progressive Motility (%) (including rapidly and slowly progressive motility) were directly reported as the 5th percentile in the *WHO Laboratory Manual for the Examination and Processing of Human Semen*, 6th Edition (Table 8.3). The lower limit of the reference range for parameters Motile Sperm Concentration and Progressive Motile Sperm Concentration (including Rapid and Slow PMSC) were calculated as the 5th percentile based on the raw data from the study conducted by Campbell et al[1].

Reference Values for Semen Parameters		
SEMEN PARAMETER	**REFERENCE RANGE**	**SOURCE**
TOTAL SPERM CONCENTRATION, M/mL	≥ 16	WHO 6th Edition
TOTAL MOTILITY (PR+NP), %	≥ 42	
PROGRESSIVE MOTILITY (PR), % (RAPIDLY PROGRESSIVE + SLOWLY PROGRESSIVE MOTILITY)	≥ 30	
MOTILE SPERM CONCENTRATION (MSC), M/mL	≥ 7.0	
PROGRESSIVELY MOTILE SPERM CONCENTRATION (PMSC), M/mL	≥ 5.0	

C Other Supportive Instrument Performance Characteristics Data:

1. Sample Stability

A sample stability study was performed to demonstrate stability of labile motility-related semen parameters in different time intervals. Ten random liquified native semen samples were assessed in duplicate by two operators using two YO 3 devices with two lots of testing YO slides and one SQA-V comparator device with two lots of testing capillaries in the following time intervals of sample collection: one hour, two hours, three hours, and four hours. Averages of motility-related semen parameters (total motility, MSC and PMSC) were assessed at the time intervals and their results were compared to their initial (T0) results. The study results support the recommendations as per the WHO 6th Edition to perform semen analysis on the YO 3 within one hour of collection.

2. Detection Limit

A study was conducted to determine the detection limits of the sperm concentration analyzed with the YO Home Sperm Test. Blank seminal plasma was used to represent a surrogate for the blank sample. Low level semen samples were prepared by pooling three donor semen samples and concentrating sperm via centrifugation and removal of the supernatant. The cell pellet was resuspended in seminal plasma to a concentration of approximately 2–8 M/mL as verified by microscope. Results were calculated and the detection limits were determined to be:

[1] Campbell MJ, Lotti F, Baldi E, Schlatt S, Festin MP, Bjorndahl L et al. Distribution of Semen Examination Results 2020 - a follow up of data collated for the WHO semen analysis manual 2010. Andrology. 2021.

Limit of Blank (LoB) = 0.00 M/mL
Limit of Detection (LoD) = 1.74 M/mL
Limit of Quantitation (LoQ) = 1.74 M/mL

3. User Comprehension Study
   As part of the method comparison study, the sponsor conducted a user comprehension study by issuing a post-test questionnaire and a user comprehension quiz. The post-test questionnaire consisted of six questions and was completed by 315 participants. The percentage distribution of results for responses of the 5-point Likert scale are reported. The results for all questions were in categories one and two approximately 98% of the time. The user comprehension quiz consisted of nine questions and was completed by 84 participants. The percentage distributions of results for responses are reported. Over 85% correct answers for all questions are reported.

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.