November 29, 2024

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

Re: K241628
Trade/Device Name: YO Home Sperm Test
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: POV
Dated: June 6, 2024
Received: June 6, 2024

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)*
K241628

Device Name
YO Home Sperm Test

Indications for Use *(Describe)*
The YO Home Sperm Test (YO 3.0) is a smartphone-based 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.

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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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

Date Created: October 14th, 2024

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

ClassificationTrade Name:
YO Home Sperm Test

Common Name: YO Home Sperm Test

Classification: Class II, POV
21 CFR 864.5220

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

The YO Home Sperm Test (YO 3.0) is substantially equivalent to two FDA-cleared predicate devices- the initial YO Home Sperm Test cleared under K161493, and the SQA-V sperm quality analyzer (SQA-V), cleared under K021746.

The YO Home Sperm Test (YO 3.0) is substantially equivalent to both devices in terms of general intended use (assessment of semen parameters), general optical technology, sample type, male fertility factor, and in vitro use.

Specifically, the YO Home Sperm Test (YO 3.0) is substantially equivalent to the initial YO Home Sperm Test in terms of intended users: Lay Users (over-the-counter) and utilization of signal/image processing. The YO Home Sperm Test is substantially equivalent to the SQA-V in terms of comparative data for the various measured and calculated parameters.

807.92 (a)(4): Device Description

The YO Home Sperm Test (YO 3.0) is a smartphone-based 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 + 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) 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 with the YO device.

The YO kit provides the supplies necessary to test up to six semen samples: semen collection cups, pipettes for sample aspiration, fixed coverslip slides, liquefaction powder and a YO device that connects via WiFi to a smartphone and houses the YO slide. The YO software app guides the user through the sample preparation and testing process step-by-step with mandatory confirmation by the user of each completed step. The app also operates the YO device's camera and processor to provide a semen video.

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. 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.

When YO reports any semen value below the cut-off for normal, YO recommends performing an additional test with a new sample and to seek medical advice. YO cut-offs are based on WHO 6th ed. reference values for semen parameters, statistical modeling, and expert publications. The user is not required to perform any interpretation of the test results and YO does not review, verify, or interpret the video provided to the operator. The user can only observe and archive his test results and sperm video. YO does not provide a comprehensive evaluation of a male's fertility status and is intended for over-the-counter), for in vitro use only.

The YO software guides the user through the testing process step by step on the smartphone's screen and operates in conjunction with the: YO device, smartphone's built-in camera, flash, and man-machine interface to report and store the results of 5 sperm parameters and a video of the user's semen samples. After analyzing the operator's semen video, the YO software reports both the quantitative results and an explanation about the 5 Semen parameters which are visually presented in the YO app directly following testing. In addition, the operator's sperm video is also presented in the test results section directly following the testing phase of the app.

807.92 (a)(5): Intended Use/Indications for Use

The YO Home Sperm Test (YO 3.0) is a smartphone-based 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.

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

The YO Home Sperm Test (YO 3.0) is substantially equivalent to two FDA-cleared predicate devices- the initial YO Home Sperm Test cleared under K161493, and the SQA-V sperm quality analyzer, cleared under K021746.

The YO Home Sperm Test (YO 3.0) is substantially equivalent to both devices in terms of general intended use (assessment of semen parameters), general optical technology, sample type, male fertility

factor, and in vitro use. Specifically, the YO Home Sperm Test (YO 3.0) is substantially equivalent to the initial YO Home Sperm Test in terms of intended users: Lay Users (over-the-counter) and utilization of signal/image processing. The YO Home Sperm Test is substantially equivalent to the SQA-V in terms of comparative data for the various measured and calculated parameters.

Element	**New product** YO Home Sperm Test (YO 3.0)	**Legal Predicate** YO Home Sperm Test: 510(k) K161493	**Functional Predicate/ Comparative Method** SQA-V: 510(k) K021746
Intended use	The YO Home Sperm Test (YO 3.0) is a smartphone-based test for semen analysis performed by lay users. The YO Home Sperm Test (YO 3.0) does not provide a comprehensive evaluation of a male's fertility status and is intended for over-the-counter in vitro use only.	The initial YO Home Sperm Test is a smartphone-based test that provides a qualitative assessment of motile sperm concentration (MSC) in human semen. MSC is one aspect of a male semen examination. The initial 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 SQA-V is an, in vitro use, electro-optical medical device with on-screen visualization for semen analysis performed by healthcare professionals (trained lab technicians).
Intended User	Lay Users (over-the-counter).	Same	Healthcare Professionals (trained lab technicians)
WHO compliance	WHO 6th	WHO 5th	WHO 5th and WHO 6th
Sample type	Human semen	Same	Same
Male fertility factor	Yes	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	<u>Parameters measured/ Reported:</u> • 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)	<u>Parameters Measured/ Reported:</u> • 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.	<u>The Parameters measured/ reported that overlap with the YO Home Sperm Test (YO 3.0):</u> • 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

Element	New product YO Home Sperm Test (YO 3.0)	Legal Predicate YO Home Sperm Test: 510(k) K161493	Functional Predicate/ Comparative Method SQA-V: 510(k) K021746
Technology	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 the smartphone.	Magnification "Clip" 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).	Desktop unit consists of a light source, optical sensors, 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.

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 YO Home Sperm Test (YO 3.0). These studies were all performed in-house and included evaluations for:

- Precision (user repeatability and laboratory reproducibility)
- Detection limits (LOB/LOD [LOD = LOQ])
- Linearity
- Specificity/Interference

All the studies utilized native human semen samples, with some samples being manually prepared (diluted or spiked) 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 (user repeatability)

In a 3-site study, approximately 20 users per site collected their own semen samples and tested the samples in triplicate. The study included three batches (lots) of slides- one per site. After the initial test, the users tested their sample two more times using a new slide.

This study only reported the directly measured parameters of sperm concentration, motile sperm concentration (MSC), progressively motile sperm concentration (PMSC).

The statistical analyses calculated means, standard deviations (SDs) and percent coefficients of variation (%CVs) per sample. Then, group SDs and %CVs were calculated from samples where the means were categorized as arbitrary low, middle, and high for sperm concentrations.

Note: Native samples were analyzed in a prospective manner without the requirement to obtain full dynamic range representation for each parameter.

Within-run Repeatability Summary (in %CV) is presented in the table below, for all three sites:

Site	Concentration	MSC	PMSC
VN	6.7%	4.6%	7.4%
NH	9.7	9.6	11.8
EN	7.9%	5.9%	7.7%

For between-run repeatability, it was demonstrated that SDs for sperm concentration were <20 SD in all cases, and were within 10 SD for MSC and PMSC in all cases except for one.

Precision- (professional user reproducibility)
In the same 3-site study as described for repeatability, three trained operators (professional users) followed the CLSI EP05-A3 standard, using the variation 3x5x5 scheme guidance as follows: at least 15 native semen samples representing 3 levels of sperm concentration, MSC, and PMSC, x 2 reps per sample x 4 time points x 3 YO devices (one per operator) = 360 measurements total, 24 results per sample. Three batches of YO slides (one per device) were included.

A total of 15-30 native semen samples were collected per WHO 6th ed. manual representing three levels and the three measured paraments, as per the table below:

Precision (Reproducibility) Range Coverage Table						
Sample Level	**# of Samples**	**# of Replicates**	**# of Tests**	**Target Concentration, M/mL**	**Target MSC, M/mL**	**Target PMSC, M/mL**
Low	5	2	10	<16	<7	<5
Medium	5	2	10	16-66	7-42	5-36
High	5	2	10	67-100	43-80	37-76

The study results demonstrated %CVs of less than 20% for all samples and for all measured parameters, with the exception of two cases with %CVs of 20.8% and 23.2%. These data were generated with the same operator and YO device combination, but the same combination achieved excellent precision with other samples. This points to some instability or artifact in the sample.

Analytical Sensitivity- Detection Limits (LoD/ LoB/ LoQ)

The objective of this study was to define the limit of blank and limit of detection of the YO Home Sperm Test (YO 3.0) for sperm concentration. In this study, the LoD was defined the LoQ.

The study included two samples, a blank (seminal plasma) and a low sample, five YO3 devices, two lots of YO slides, and two operators. The reported parameter was sperm concentration and the study followed CLSI EP17-A2 guidelines. The samples were assayed 12 times on each of five YO3 devices, 60 results per level.

Three donor semen samples were pooled and centrifuged to obtain sperm-free seminal plasma to a concentration of ~0 M/mL (blank sample) as verified by manual microscope. The low concentration sample was prepared by re-suspending part of the sperm pellet in seminal plasma to a concentration of ~2 – 8 M/mL, as verified by microscope.

It was demonstrated that the LoD/Q is greater than the LoB, and the LoD/Q is lower than the lower end of the concentration range (2 M/mL), as per MES reportable ranges claims and WHO 6th reference range for concentration.

Linearity

The dynamic range and linearity of the YO device was established by using three YO devices and one SQA-V reference system. Semen samples were prepared at ten semen concentration intervals ranging from low to high level (less than 2 to 150 M/mL). The test was performed in three YO 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 YO Home Sperm Test (YO 3.0) linear regression coefficients "R" exceeds the MES claim of 0.9.

Furthermore, it was demonstrated that the YO Home Sperm Test (YO 3.0) slope exceeds the acceptance criteria of 1.0 +/- 0.2. The results support the claim that the YO Home Sperm Test (YO 3.0) candidate device, generates linear concentration results from 2 to 150 M/mL.

Interference Study

The objective of the study is to determine if the YO3 clinical results are significantly impacted by spiking the semen samples with a variety of biological components (contaminants) and comparing the results to a control, supplemented with seminal plasma only.

The interference study was performed using two concentration levels (20-60 and 60-100 x 10^6/mL) of semen samples and 11 potentially interfering substances (vitamin B, testosterone, yeast, E. coli, RBC, WBC, urine, saliva, agglutination of semen sample, D-norgestrel, and β-estradiol).

It was found that results of the semen parameters assessed using spiked samples were within 15% of the controls. The percent differences were both positive and negative, suggesting random variation and not systematic bias.

The study results indicate that all tested 11 interference substances meet CLSI EP07, 3rd ed. acceptance criteria for therapeutic levels of concentration. It was demonstrated that the tested substances do not cause significant interference.

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

The clinical validation was a method comparison study that confirmed the clinical equivalence between human semen sample results on the YO 3.0 Home Sperm Test (YO) device operated by INTENDED USERS vs. test results obtained on the SQA-V comparator device operated by TRAINED OPERATORS. Each semen sample was tested in singleton in a blinded fashion by each method using split aliquots.

The study was conducted with IRB oversight at three US sites where lay users were recruited. The INTENDED USERs analyzed their own samples using the YO 3.0 device. In addition, some female

INTENDED USERS were enrolled to test donor semen samples;

The study included 309 comparative data sets overall, with a minimum of 100 semen samples per site. The lay users performed their testing without active training; training was limited to referencing the Instructions for Use included in the YO kit and viewing a HOW YO WORKS video that is available on the YO interface as part of the commercialized system.

Following testing, each lay user completed an exit questionnaire probing opinions of the procedural steps using the 5-point Likert scale.

Statistical Methods

The side-by-side data (YO vs SQA-V) were analyzed using Passing-Bablok regression with SQA-V (reference) results on the x-axis, and the YO results on the y-axis.

***Study Results*- Passing-Bablok Regression Data**

The summarized regression data and graphs for all sites and from all parameters are shown in the table below. The slopes for the directly measured parameters of concentration, MSC and PMSC were 0.86, 0.92, and 1.03, respectively, and the y-intercepts were 2.29, 1.84, and -0.04. The "r"s were >0.9 for all three directly measured parameters. For the calculated parameters (%motility and %progressive motility), the slopes were 1.05 and 1.24, respectively, and the y-intercepts were 0.00 and -0.47. The "r"s were 0.9 and 0.88.

YO Intended User vs. SQA-V Expert User (n = 309)

CONCENTRATION					
Intercept	95% CI	Slope	95% CI	Correlation	95% CI
2.29	1.29 to 3.25	0.86	0.82 to 0.91	0.93	0.92 to 0.95

MOTILITY, %					
Intercept	95% CI	Slope	95% CI	Correlation	95% CI
0.00	0.00 to 3.00	1.05	1.00 to 1.11	0.90	0.88 to 0.92

PROGRESSIVE MOTILITY, %					
Intercept	95% CI	Slope	95% CI	Correlation	95% CI
-0.47	-2.78 to 0.00	1.24	1.16 to 1.31	0.88	0.85 to 0.90

MOTILE SPERM CONCENTRATION, M/ml					
Intercept	95% CI	Slope	95% CI	Correlation	95% CI
1.84	1.50 to 2.20	0.92	0.88 to 0.95	0.94	0.93 to 0.95

PROGRESSIVELY MOTILE SPERM CONCENTRATION, M/ml					
Intercept	95% CI	Slope	95% CI	Correlation	95% CI
-0.04	-0.44 to 0.00	1.03	0.98 to 1.07	0.94	0.92 to 0.95

Intended User Overall Demographics (n = 315)

The diversity of the United States intended use population was reflected in the study. The following information was requested of each subject enrolled in the study: gender, age, ethnicity and educational level. Overall demographics is summarized in the table below:

	Site 1	**Site 2**	**Site 3**	**All sites**
Gender (Testers)	115	115	85	315
Male	108 (93.9%)	104 (90.4%)	85 (100%)	297 (94.2%)
Female	6 (5%)	7 (6%)	0	13 (4.1%)

Other	1 (<1%)	4 (3.4%)	0	5 (1.6%)
Age (years)				
18-28	25 (21.7%)	38 (33%)	23 (27%)	86 (27.3%)
29-38	54 (47%)	43 (37.3%)	42 (49.4%)	139 (44.1%)
39-45	28 (24.3%)	22 (19.1%)	13 (15.3%)	63 (20%)
45 and above	3 (2.6%)	8 (7%)	5 (5.9%)	16 (5%)
Did Not Answer	5 (4.3%)	4 (3.5%)	2 (2.4%)	11 (3.5%)
Average Age	33	33	33	33
Min-Max	20-61	18-71	20-51	18-71
Education				
High School or Less	42 (36.5%)	36 (31.3%)	35 (41.2%)	97 (30.8%)
College	51 (44.3%)	54 (46.9%)	39 (45.9%)	144 (45.7%)
AA Degree	9 (7.8%)	16 (13.9%)	14 (16.5%)	39 (12.4%)
Masters	10 (3.2%)	7 (6%)	11 (12.9%)	28 (8.9%)
Did not Respond	3 (2.6%)	2 (1.7%)	2 (2.4%)	7 (2.2%)
Ethnicity				
Asian	11 (9.6%)	7 (6%)	8 (9.4%)	26 (8.3%)
Black	19 (16.5%)	16 (13.9%)	14 (16.4%)	49 (15.6%)
Caucasian	34 (29.6%)	53 (46%)	33 (38.8%)	120 (38%)
Hispanic	49 (42.6%)	33 (28.7%)	22 (25.9%)	104 (33%)
Other / Do not wish to report	0	4 (3.5%)	7 (8.2%)	11 (3.5%)
Did not answer	2 (1.7%)	2 (1.7%)	1 (1.2%)	5 (1.6%)

Post- Test Questionnaire

Results from the 5-question questionnaire were summarized descriptively, for a total of 84 participants. The percentage distributions of results for responses of the 5-point Likert scale are reported. The questions are shown below each question number, and the data are reported for all sites combined.

Question #1: Sperm CONCENTRATION (M/mL) is:		
	ANSWER	RESPONSE %
A.	The number of sperm in the collection cup	5%
B.	**The number of sperm in 1mL of your sample**	90%
C.	The number of live sperm	5%
D.	The number of abnormally shaped sperm	0%

Question #2: Sperm MOTILITY (%) is:		
	ANSWER	RESPONSE %
A.	**The % of all moving sperm in your sample, even those wiggling in place and moving in all directions**	87%
B.	The % of sperm moving in only one direction	13%
C.	The % of sperm moving backwards	0%
D.	The % of sperm that are not moving	0%

Question #3: Sperm PROGRESSIVE MOTILITY (%) is:		
	ANSWER	RESPONSE %
A.	The % of sperm with multiple heads	4%
B.	**The % of only forward moving sperm in your sample**	96%
C.	The % of sperm that are not moving	0%

D.	The % of sperm moving backwards	0%

Question #4: MOTILE SPERM CONCENTRATION (MSC) M/mL is:		
	ANSWER	RESPONSE %
A.	The number of sperm with abnormal shapes	0%
B.	The number of moving sperm in the collection cup	6%
C.	The number of sperm moving backwards	0%
D.	**The number of moving sperm in 1mL of your sample**	94%

Question #5: PROGRESSIVELY MOTILE SPERM CONCENTRATION (PMSC) M/mL is:		
	ANSWER	RESPONSE %
A.	**The number of sperm moving forward in 1ml of your sample**	97%
B.	The number of sperm with abnormal shapes in 1 mL of your sample	1%
C.	The number of sperm moving backwards in 1 mL of your sample	0%
D.	The number of sperm moving forward in the collection cup	2%

Question #6: What factors may cause semen quality to change from time to time?		
	ANSWER	RESPONSE %
A.	My lifestyle habits such as smoking, drinking, overeating resulting in obesity	12%
B.	Taking hormones such as testosterone or body enhancing steroids	0%
C.	A recent illness with high fevers or requiring chemotherapy	0%
D.	**All of the above are correct**	88%

Note: Only answer D is considered as correct

Question #7: If all of your results are NORMAL and you've been trying to conceive for over a year, what should you do?		
	ANSWER	RESPONSE %
A.	Consider talking to your doctor or a fertility expert with your partner	12%
B.	There is nothing to do	1%
C.	Understand that YO is a screening device, and a more extensive semen analysis might be useful	0%
D.	**Both A and C are correct**	87%

Question #8: Your first YO Home Sperm Test shows all test results are LOW, what should you do?		
	ANSWER	RESPONSE %
A.	**Consider repeating your YO test in 2-4 weeks and modifying your lifestyle habits such as: Smoking, alcohol and recreational drug use.**	99%
B.	Do nothing	0%

C.	Share results with friends who have had fertility problems for advice.	0%
D.	Repeat your YO test the next day.	1%

Question #9: Your second YO Home Sperm Test shows all test results as NORMAL, but you have not conceived in a year. What should you do?		
	ANSWER	RESPONSE %
A.	Repeat your YO test the next day	0%
B.	There is nothing you can do but keep trying	1%
C.	**Consider talking to your doctor or a fertility expert, because infertility can be a male and a female problem**	99%
D.	Share results with friends who have had fertility problems for their advice	0%

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

The YO Home Sperm Test (YO 3.0) 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 YO Home Sperm Test (YO 3.0) is safe and performs effectively based on its intended use.