



**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT**

I Background Information:

A 510(k) Number

K252228

B Applicant

CheckCells, Inc.

C Proprietary and Established Names

Seaman PRO

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 new device.

B Measurand:

Sperm concentration (M/mL), total motility (%), progressive motility (%), morphology (%), pH, and Vitality (%)

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 Seaman PRO Analyzer is an automated, point-of-care, in vitro use-only medical device for semen analysis performed by healthcare professionals. The desktop unit consists of a light source, optical elements, and an image sensor connected to a PC, which records a video of the semen sample and sends it to the cloud compute unit. The cloud compute unit runs software containing algorithms for assessing semen parameters. The product is a software-based medical device powered by ML that enables the user to further assess semen parameters, including concentration, motility, pH, morphology, and vitality. The product is intended for adult male patients to assess sperm quality. The product is not intended to process any of the PHI/PII. Seaman PRO for prescription use only.

Seaman PRO used with Imaging Hardware is an optical device for human semen analysis, which provides direct and calculated quantitative measurements for:

1. Sperm concentration (10^6 per ml)
2. Total motility (PR+NP, %)
3. Progressive motility (%)
4. pH value
5. Sperm morphology (normal forms, %)
6. Vitality (%).

The Seaman PRO device does not provide a comprehensive evaluation of a male's fertility status. Instead, it analyzes semen parameters that healthcare professionals use as part of a broader assessment of male fertility.

C Special Conditions for Use Statement(s):

Rx Only

D Special Instrument Requirements:

Seaman PRO System

IV Device/System Characteristics:

A Device Description:

The Seaman PRO System is an automated in vitro diagnostic device for human semen analysis consisting of imaging hardware and software components designed for use in the point-of-care setting. The devices are intended for use in adult male individuals and are not to be used for post-vasectomy confirmation or in the diagnosis or treatment of disease. The device is intended for

multiple uses and does not require patient-contact reprocessing. Only single-use sample carriers come into direct contact with the biological material. The reusable imaging hardware does not require sterilization and is cleaned using standard laboratory procedures. The Seaman PRO kit includes the following components for analysis: Imaging Hardware (for precise camera positioning, sample illumination and image capturing), Power cable (for light source), Camera cable (for image recognition), Cartridge for pH strip, and scale (informational purposes only).

B Principle of Operation:

For both the Seaman and Seaman PRO Systems, the imaging hardware includes a desktop optical unit composed of a light source, fixed optical elements, and a digital image sensor. The unit captures video recordings of semen samples prepared on sperm counting microscopic slides. The acquired image data is transferred to a connected PC and processed in a secure cloud compute environment. The software component is a Software as a Medical Device (SaMD) that uses image analysis algorithms, including machine learning (ML) techniques, to quantify semen parameters, including:

- Sperm concentration ($10^6/\text{mL}$),
- Total Motility (%),
- Progressive Motility (%),
- Sperm morphology (% normal forms),
- pH value,
- Vitality (%).

Analysis of semen parameters require minimal sample manipulation. However, Vitality (%) is determined using WHO laboratory manual for the examination and processing of human semen, 6th edition Eosin-Nigrosin Stain procedure. A smear is prepared on a glass slide from fresh liquefied semen samples mixed with equal volume of eosin-nigrosin staining solution. Once dry, the stained slides are immediately analyzed on the Seaman PRO System.

The device provides quantitative outputs based on video analysis of sperm. The software does not interpret results or diagnose fertility status. It is intended to support healthcare professionals in assessing semen quality. The device does not process, store, or transmit any Protected Health Information (PHI) or Personally Identifiable Information (PII).

C Instrument Description Information:

1. Instrument Name:

Seaman PRO System

2. Specimen Identification:

Manual Data Entry

3. Specimen Sampling and Handling:

The semen specimen should be collected via masturbation directly into a sterile, wide-mouthed, non-toxic, and appropriately labeled container made of polypropylene or polystyrene, in accordance with WHO laboratory manual recommendations. No lubricants or spermicidal agents should be used. The entire ejaculate should be collected, ensuring the first portion (rich in spermatozoa) is not lost. After collection, the sample must rest undisturbed at room temperature for approximately 15-30 minutes to allow for natural liquefaction. Incomplete liquefaction may affect analysis accuracy. The sample should be analyzed within 60 minutes of ejaculation for optimal accuracy. Delays in analysis beyond 60 minutes may result in decreased motility and alterations in morphology or pH. Samples should not be refrigerated or frozen prior to analysis.

4. Calibration:

User calibration is not required.

5. Quality Control:

The quality control of the device should be performed regularly and at least once a month. The quality can be controlled on a hardware level and on a software level.

Hamilton Thorne Accu-beads: three concentration levels (low, medium, high) of silicone beads, similar in size to human sperm, suspended in an aqueous solution.

Fertility Solutions Semen Test Recordings: control material represented by a set of microscopic recordings of human semen with three levels (low, medium, high) of motility, morphology, and vitality.

V Substantial Equivalence Information:

A Predicate Device Name(s):

LensHooke X1 Pro Semen Quality Analyzer

B Predicate 510(k) Number(s):

K180343

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K252228</u>	<u>K180343</u>
Device Trade Name	Seaman PRO System	LensHooke X1 Pro Semen Quality Analyzer

General Device Characteristic Similarities		
Intended Use/Indications For Use	The Seaman PRO Analyzer is an automated, point-of-care, in vitro use-only medical device for semen analysis performed by healthcare professionals. The desktop unit consists of a light source, optical elements, and an image sensor connected to a PC, which records a video of the semen sample and sends it to the cloud compute unit. The cloud compute unit runs software containing algorithms for assessing semen parameters. The product is a software-based medical device powered by ML that enables the user to further assess semen parameters, including concentration, motility, pH, morphology, and vitality. The product is intended for adult male patients to assess sperm quality. The product is not intended to process any of the PHI/PII. Seaman PRO for prescription use only. Seaman PRO used with Imaging Hardware is an optical device for human semen analysis, which provides direct and calculated quantitative measurements for:	The LensHooke X1 PRO Semen Quality Analyzer used with LensHooke Semen Test Cassette is an optical device for human semen analysis which provides direct and calculated quantitative measurements for: (1) Sperm concentration (10^6 per ml) (2) Total motility (PR+NP, %) • Progressive motility (%) • Non-Progressive motility (%) (3) Sperm morphology (normal forms, %) (4) pH value. The LensHooke X1 PRO Semen Quality Analyzer does not provide a comprehensive evaluation of a male's fertility status. It is an in-vitro diagnostic system intended for human semen analysis of individuals in healthcare professional setting to evaluate male fertility.

	1. Sperm concentration (10⁶ per ml) 2. Total motility (PR+NP, %) 3. Progressive motility (%) 4. pH value 5. Sperm morphology (normal forms, %) 6. Vitality (%). The Seaman PRO device does not provide a comprehensive evaluation of a male's fertility status. Instead, it analyzes semen parameters that healthcare professionals use as part of a broader assessment of male fertility.	
Regulation (product code)	21 CFR 864.5220 (POV)	Same
Sample Type	Human Semen	Same
Parameters	Sperm concentration, motility (total, progressive), morphology, pH	Same
Test Principles	Optical design and Image processing method, Image analysis	Same
Software Algorithm	Custom image analysis with AI	Similar
Test Locale	POC	Same
General Device Characteristic Differences		
Standard/ Guidance Document	WHO 6th edition guidelines	WHO 5th edition guidelines
Consumables	GoldCyto semen analysis slides	Semen Test Cassette (CS0, CS1)
Hardware Configuration	Camera + optics + PC with AI software (modular)	Integrated desktop analyzer
Different Parameters	% Vitality, Semen	Nonprogressive

	Volume, Total Sperm Count	Motility
Testing requiring additional reagents / slide from end-user (not provided)	% Vitality procedure	None
Control Material	Hamilton Thorne Accu-beads	X QC Beads, X QC Reticle
	Fertility Solutions Semen Test Recordings	LensHooke X QC Video (For Semen)

VI Standards/Guidance Documents Referenced:

WHO Laboratory Manual for the Examination and Processing of Human Semen 6th Edition (2021)

CLSI EP05-A3 (2014): Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline - Third Edition

CLSI EP06-A2 (2020): Evaluation of the Linearity of Quantitative Measurement Procedures; Approved Guideline - Second Edition

CLSI EP07 (2018): Interference Testing in Clinical Chemistry; Approved Guideline - Third Edition

CLSI EP25-A2 (2023): Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline - Second edition

CLSI EP09-c (2018): Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline - Third Edition

CLSI EP17-A2 (2012): Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline - Second edition

CLSI EP21 (2016): Evaluation of Total Analytical Error for Quantitative Medical Laboratory Measurement Procedures; Approved Guideline - second edition

CLSI EP15-A3 (2019): Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline - Second Edition

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Repeatability

A precision study was conducted evaluating sperm concentration, motility, progressive motility, morphology, pH, and vitality using fourteen native semen samples covering low, medium, and high ranges for all parameters. Some samples were only utilized for certain parameters (i.e. pH and vitality) due to limited sample stability, but at least seven samples were used for each parameter evaluation. The analysis was carried out at one POC site over the course of one day by two POC operators using three lots, and three analyzers. Due to the limited stability of semen samples, each “day” in the statistical analysis represents different times of the one day. The study included two replicates per run with 2 runs per 20 “days” (all over one actual day) (20 “days” × two replicates × two runs = 80 data points per level). Data analyses were performed to provide within-run, between-run, between-day, within-laboratory, between-operator, between-instrument, and between-lot repeatability. All results met the predefined acceptance criteria.

Concentration [M/mL]																
ID	Mean Value	n	Within-Run		Between-Run		Between-Day		Within-Laboratory		Between Operator		Between Instrument		Between Lot	
			CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD
1	131.3	80	6.5	1.1	5.8	1.0	3.9	0.7	8.4	1.4	1.3	0.2	1.8	0.3	1.3	1.7
2	12.9	80	7.2	5.9	5.0	4.1	2.9	2.4	8.2	6.7	1.8	1.4	1.4	1.2	1.2	0.2
3	51.8	80	3.9	2.5	5.2	3.4	3.4	2.2	6.2	4.0	1.6	1.1	2.0	1.3	0.5	0.3
4	7.0	80	5.6	3.9	4.8	3.4	3.8	2.7	6.9	4.9	0.7	0.5	0.6	0.5	1.3	0.1
5	36.9	80	6.0	5.3	5.4	4.8	3.4	3.0	7.4	6.5	1.6	1.4	1.1	1.0	3.3	1.2
6	179.3	80	6.5	2.4	5.8	2.1	3.0	1.1	8.0	3.0	1.1	0.4	0.3	0.1	0.2	0.4
7	95.2	80	5.3	3.0	4.9	2.8	3.3	1.9	7.0	4.0	2.1	1.2	2.0	1.2	2.4	2.3

Total Motility [%]																
ID	Mean Value	n	Within-Run		Between-Run		Between-Day		Within-Laboratory		Between Operator		Between Instrument		Between Lot	
			CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD
1	53.9	80	6.1	3.3	5.2	2.8	3.5	1.9	7.5	4.1	0.9	0.5	0.9	0.5	1.4	0.8
2	30.5	80	6.4	2.0	5.1	1.5	3.9	1.2	7.6	2.3	0.1	0.0	1.4	0.4	0.6	0.2
3	73.1	80	5.9	4.3	5.8	4.3	4.3	3.1	7.7	5.7	1.4	1.0	3.2	2.4	1.7	1.3
4	61.1	80	5.6	3.4	6.1	3.7	4.7	2.8	7.7	4.7	0.5	0.3	1.0	0.6	1.7	1.1
5	24.1	80	6.6	1.6	6.6	1.6	5.7	1.4	8.6	2.1	0.9	0.2	1.7	0.4	2.8	0.7
6	84.5	80	4.9	4.1	4.3	3.6	2.8	2.4	6.3	5.3	0.6	0.5	0.2	0.2	2.5	2.1
7	47.4	80	5.9	2.8	5.2	2.5	3.1	1.5	7.5	3.5	1.6	0.7	1.8	0.9	1.2	0.6

Progressive Motility [%]																
ID	Mean Value	n	Within-Run		Between-Run		Between-Day		Within-Laboratory		Between Operator		Between Instrument		Between Lot	
			CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD
1	48.4	80	7.3	3.6	6.2	3.0	3.7	1.8	8.8	4.2	0.1	0.1	1.6	0.8	1.1	0.6
2	24.6	80	8.1	2.0	6.5	1.6	4.9	1.2	9.3	2.3	0.1	0.0	1.6	0.4	0.4	0.1
3	62.3	80	6.9	4.3	6.6	4.1	4.6	2.9	9.2	5.7	1.4	0.9	3.5	2.2	1.2	0.7
4	52.1	80	7.0	3.7	6.0	3.1	4.8	2.5	8.5	4.4	0.5	0.3	1.2	0.6	2.1	1.1
5	20.5	80	8.4	1.7	6.4	1.3	5.2	1.1	9.4	1.9	1.3	0.3	2.2	0.4	2.3	0.5
6	71.3	80	5.8	4.2	5.9	4.2	4.1	2.9	7.9	5.6	0.5	0.4	0.8	0.5	2.8	2.0
7	40.8	80	6.4	2.6	5.9	2.4	3.6	1.5	8.1	3.3	0.8	0.3	2.0	0.8	1.7	0.7

Morphology [%]																
ID	Mean Value	n	Within-Run		Between-Run		Between-Day		Within-Laboratory		Between-Operator		Between-Instrument		Between-Lot	
			CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD
1	2.7	80	6.4	0.2	6.4	0.2	3.6	0.1	8.6	0.2	3.5	0.09	1.0	0.03	1.3	0.03
2	4.3	80	6.6	0.3	5.1	0.2	3.8	0.2	7.6	0.3	0.0	0.00	1.4	0.06	2.2	0.09
3	8.6	80	4.9	0.4	4.5	0.4	2.7	0.2	6.3	0.5	0.6	0.05	1.7	0.14	1.2	0.11
4	2.5	80	7.3	0.2	5.3	0.1	4.2	0.1	8.1	0.2	1.1	0.03	2.1	0.05	1.2	0.03
5	14.2	80	4.2	0.6	4.2	0.6	2.9	0.4	5.6	0.8	1.1	0.15	1.1	0.15	0.6	0.09
6	3.5	80	8.2	0.3	4.9	0.2	3.2	0.1	8.2	0.3	1.6	0.06	0.7	0.03	1.5	0.05
7	4.6	80	6.4	0.3	5.6	0.3	4.3	0.2	7.9	0.4	0.0	0.00	0.7	0.03	2.3	0.11

Vitality [%]																
ID	Mean Value	n	Within-Run		Between-Run		Between-Day		Within-Laboratory		Between-Operator		Between-Instrument		Between Lot	
			CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD
8	17.2	80	6.5	1.1	5.8	1.0	3.9	0.7	8.4	1.4	1.3	0.2	1.8	0.3	0.6	0.1
9	81.8	80	7.2	5.9	5.0	4.1	2.9	2.4	8.2	6.7	1.8	1.4	1.4	1.2	0.5	0.4
10	65.6	80	3.9	2.5	5.2	3.4	3.4	2.2	6.2	4.0	1.6	1.1	2.0	1.3	1.8	1.2
11	70.9	80	5.6	3.9	4.8	3.4	3.8	2.7	6.9	4.9	0.7	0.5	0.6	0.5	0.7	0.5
12	88.7	80	6.0	5.3	5.4	4.8	3.4	3.0	7.4	6.5	1.6	1.4	1.1	1.0	0.4	0.4
13	37.0	80	6.5	2.4	5.8	2.1	3.0	1.1	8.0	3.0	1.1	0.4	0.3	0.1	1.0	0.4
14	57.4	80	5.3	3.0	4.9	2.8	3.3	1.9	7.0	4.0	2.1	1.2	2.0	1.2	0.9	0.5

pH																
ID	Mean Value	n	Within-Run		Between-Run		Between-Day		Within-Laboratory		Between-Operator		Between-Instrument		Between Lot	
			CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD
8	7.8	80	7.6	0.6	5.8	0.5	3.6	0.3	8.9	0.7	0.4	0.0	1.4	0.1	1.2	0.1
9	8.4	80	4.8	0.4	4.2	0.4	3.4	0.3	6.2	0.5	1.4	0.1	0.6	0.1	1.7	0.1
10	7.8	80	5.1	0.4	4.3	0.3	2.8	0.2	6.4	0.5	0.7	0.1	1.2	0.1	0.8	0.1
11	6.8	80	5.6	0.4	6.3	0.4	5.1	0.3	7.9	0.5	0.9	0.1	0.9	0.1	1.1	0.1
12	8.3	80	4.5	0.4	4.9	0.4	3.6	0.3	6.3	0.5	1.2	0.1	1.1	0.1	1.4	0.1
13	7.4	80	5.9	0.4	5.6	0.4	4.1	0.3	7.7	0.6	1.8	0.1	1.7	0.1	2.3	0.2
14	8.6	80	8.0	0.7	4.7	0.4	3.6	0.3	8.2	0.7	0.5	0.0	1.7	0.1	0.3	0.0

Reproducibility

To evaluate the reproducibility performance of the Seaman PRO System, a precision study was conducted at three sites (two US, one OUS) with six POC operators. For sperm concentration and vitality, three levels of QC control solution or slides (low negative, low positive, high positive) were evaluated. For the pH evaluation, three potassium/sodium phosphate buffer levels were utilized. The studies included three sites × five replicates × five days, totaling 75 data points per level. Data analyses were performed for each site and overall to provide within-day repeatability, between-day, between-Operator, between-site, and total reproducibility. All results met the predefined acceptance criteria.

Parameter [units]	Level	N	Mean	Reproducibility									
				Within-Day		Between-Day		Between Site		Between Operator		Reproducibility	
				SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
Conc [M/mL]	3	75	3.2	0.2	6.4	0.1	4.5	0.1	2.1	0.1	2.4	0.3	7.9
	18	75	17.8	1.1	6.0	0.5	3.0	0.2	1.3	0.2	1.4	1.1	6.4
	35	75	36.1	1.7	4.6	0.8	2.3	0.5	1.5	0.7	1.8	1.8	4.9
pH	7.0	75	7.1	0.6	8.3	0.3	4.0	0.1	1.4	0.2	2.6	0.6	8.8
	8.0	75	8.0	0.5	6.1	0.2	2.7	0.1	1.5	0.1	1.6	0.5	6.7
	9.0	75	8.9	0.5	5.5	0.3	3.9	0.1	1.3	0.2	1.9	0.6	6.4
Vitality [%]	16	75	16.3	1.5	9.2	0.7	4.5	0.3	1.9	0.6	3.4	1.6	9.8
	70	75	71.6	4.3	6.0	1.9	2.7	0.7	1.0	1.1	1.5	4.6	6.4
	81	75	79.3	5.4	6.8	2.6	3.3	0.3	0.4	1.1	1.4	5.7	7.1

2. Linearity:

Linearity for sperm concentration, pH, and vitality were evaluated using one analyzer to measure semen samples prepared at nine levels. Sperm concentrations, prepared via concentration or dilution of fresh semen samples, ranged from 2.1–387.1 M/mL (n=3), verified using manual microscope. Sperm pH ranged from 6.0–9.0 (n=3), verified using manual pH strip. The different levels of pH were created by mixing different levels of semen with phosphate buffer (pH 5.0 and pH 9.0). For Vitality, commercial Sperm Viability Quality Control stained slides, with known vitality levels were utilized. For all parameters, the mean and SD of results were calculated; and Weighted Least Squares Regression analysis was used to verify the linear range. Sperm concentration was demonstrated to be linear from 2.1–387.1 M/mL, Sperm pH was demonstrated to be linear from 6.0–9.0, and sperm vitality was demonstrated to be linear from 5–81 %.

3. Analytical Specificity/Interference:

The potential interference of various substances on Seaman PRO results were evaluated by using two sperm concentration levels (< 50 M/mL and > 50 M/mL). The following 11 interfering substances were tested in the study: vitamin B, testosterone, yeast, E. Coli, RBC, WBC, urine, saliva, agglutination of semen sample, D-norgestrel, and β -estradiol. Samples were tested in five replicates on one analyzer using one lot of test slides. Results of test group were compared to the control group. Study results showed that all tested interfering substances met the acceptance criteria, and no significant interference was caused by the tested substances.

4. Detection Limit and Assay Reportable Range:

Detection Limit:

A study was conducted to determine the detection limits of the Seaman PRO System. Semen samples were taken from volunteers. For the limit of blank (LoB), semen was centrifuged to obtain sperm-free seminal plasma to a concentration of ~0 M/mL (blank sample) as verified by manual microscope. For assessing limit of detection (LoD), samples were prepared by diluting semen with seminal plasma to four samples with concentration of ~2-8 M/mL. Blank and low-level samples were divided into four aliquots and tested in five replicates once a day for three days, using one analyzer. For assessing LoQ, samples were prepared by diluting semen with seminal plasma to four samples with concentration of approximately ~2 M/mL.

The four LoQ low-level samples were tested in three replicates once a day for three days, using one analyzer and two lots of sperm counting slides.

Results were calculated, and the detection limits were determined to be:

Limit of Blank (LoB) = 0.0 M/mL

Limit of Detection (LoD) = 1.9 M/mL

Limit of Quantitation (LoQ) = 2.1 M/mL.

Assay Reportable Range:

Sperm concentration: 2.1–380 M/mL

Vitality: 1–100%

pH: 6.0–9.0

The assay reportable range was determined by the linearity and detection limit studies and verified in the method comparison study.

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

Device Stability

A stability study was conducted to determine the shelf-life of the Seaman PRO System at room temperature. Three semen samples with varying sperm concentrations (low/near cutoff, medium, high) were tested in 80 replicates using three analyzers before and after storage. The evaluation met the acceptance criteria when comparing results from the stressed devices to control analyzers. Study results demonstrated analyzer performance for three years at room temperature conditions.

Sample Stability

Stability of semen samples was determined with 42 samples at different concentration levels (half low and half high concentration samples). The semen samples were stored at room temperature. At time zero (0 hour), the samples were tested to establish the baseline. These samples were tested again at various timepoints and for each time point, the results were compared to the baseline results. The results support a 1-hour semen sample stability duration.

6. Assay Cut-Off:

See Reference Range study, section VII.D.

B Comparison Studies:

1. Method Comparison with Predicate Device:

A method comparison study was conducted to evaluate the performance of the Seaman PRO System when used by intended users (i.e. healthcare professionals). The study was performed

at three sites (two US; one OUS site), with a total of three POC operators for semen analysis. Following collection of the specimen, the operators analyzed the sample on the Seaman PRO System. After recording the results, a different operator at the study site performed semen analysis on the sample using either the predicate (i.e., the LensHooke X1 PRO Semen Quality Analyzer for concentration, motility, and morphology) or the reference method (i.e., manual microscope for % vitality analysis as recommended in the WHO 6th edition; and manual pH strip reading for pH analysis). A total of 300 semen specimens spanning the analytical measuring range were analyzed by using the Passing-Bablok regression. All results met the predefined acceptance criteria.

Seaman PRO vs. LensHooke X1 Pro					
Parameter [Units]	N	Result Range	Slope (95% CI)	Intercept (95% CI)	R ² (95% CI)
Concentration [10 ⁶ /mL]	300	3.1 - 391.3	1.04 (1.00, 1.07)	1.52 (-1.11, 4.15)	0.92 (0.91, 0.94)
Total Motility [%]	300	0 - 84	1.02 (0.99, 1.05)	-0.01 (-0.02, 0.00)	0.93 (0.92, 0.95)
Progressive Motility [%]	300	0 - 84	0.95 (0.92, 0.99)	0.02 (0.01, 0.04)	0.91 (0.89, 0.93)
Morphology [%]	300	2.7 - 7.2	1.10 (1.06, 1.14)	0.00 (-0.00, 0.00)	0.90 (0.88, 0.92)
pH	300	6.0 - 10.0	0.99 (0.96, 1.03)	0.05 (-0.25, 0.34)	0.90 (0.88, 0.92)
Vitality [%]	300	14 - 100	1.01 (0.97, 1.05)	-0.01 (-0.04, 0.02)	0.90 (0.87, 0.92)

2. Matrix Comparison:

Not applicable.

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

3. Clinical Cut-Off

Not applicable.

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

Not applicable.

D Expected Values/Reference Range:

The lower limit of the reference range for parameters Sperm Concentration (M/mL), Total Motility (%), Progressive Motility (%), Morphology (%), and Vitality (%) 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). No reference range has been established for pH.

Semen Parameter	Reference Range	Source
Sperm Concentration (M/mL)	≥ 16	WHO 6 th Edition
Total Motility (%)	≥ 42	
Progressive Motility (%)	≥ 30	
Morphology (%)	≥ 4	
Vitality (%)	≥ 54	

E Other Supportive Instrument Performance Characteristics Data:

Electrical safety and electromagnetic compatibility (EMC) testing were performed, and the system was found to be acceptable.

Software and cybersecurity documentation was reviewed and found to be acceptable.

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.