510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K242830

B Applicant

Bonraybio Co., LTD.

C Proprietary and Established Names

LensHooke X3 PRO Semen Quality Analyzer;
LensHooke X3 PRO SE Semen 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:

Clearance of new devices

B Measurand:

Sperm concentration (M/mL), Total motility (PR+NP, %), Progressive motility (%), Non-Progressive motility (%), Immotility (%), Sperm morphology (normal forms, %), and pH value

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:

For Over-the-Counter Setting:

The LensHooke X3 PRO SE Semen Quality Analyzer used with LensHooke Semen Test Cassette is an optical device for human semen analysis which provides direct and calculated measurements for:

(1) Sperm concentration (M/mL)
(2) Total motility (PR+NP, %)
- Progressive motility (%)
- Non-Progressive motility (%)
- Immotility (%)
(3) Sperm morphology (normal forms, %)
(4) pH value

The LensHooke X3 PRO SE Semen Quality Analyzer does not provide a comprehensive evaluation of a male's fertility status. It is a self-testing diagnostic system intended for human semen analysis of individuals at home to evaluate male fertility.

For Point-of-Care Professional Setting:

The LensHooke X3 PRO Semen Quality Analyzer used with LensHooke Semen Test Cassette is an optical device for human semen analysis which provides direct and calculated measurements for:

(1) Sperm concentration (M/mL)
(2) Total motility (PR+NP, %)
- Progressive motility (%)
- Non-Progressive motility (%)
- Immotility (%)
(3) Sperm morphology (normal forms, %)
(4) pH value

The LensHooke X3 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 clinical laboratories and point-of-care setting to evaluate male fertility.

C Special Conditions for Use Statement(s):
Rx and OTC

LensHooke X3 PRO Semen Quality Analyzer is intended for prescription use.
LensHooke X3 PRO SE Semen Quality Analyzer is intended for over-the-counter use.

IV Device/System Characteristics:

A Device Description:

The LensHooke X3 PRO Semen Quality Analyzer and the LensHooke X3 PRO SE Semen Quality Analyzer integrate optical design and image analysis, combined with an artificial intelligence image processing method, to fully automate the analysis of semen quality, including semen pH, sperm concentration, sperm morphology and motility. The images are captured and recorded by cameras and with image processing methods, the locations of sperm are detected.

The sperm concentration is analyzed by the sperm unit density. The sperm motility is calculated by tracing sperm trajectories. The sperm morphology is calculated by comparing head and tail percentage. The chromatographic image of pH is captured through a camera and with image saturation and brightness analysis, the level of pH is determined.

Both LensHooke X3 PRO SE Semen System and LensHooke X3 PRO Semen System consist of the following devices:

- LensHooke X3 Semen Quality Analyzer
- LensHooke CS1 Semen Test Cassette
- LensHooke X QC Beads (For Semen)
- LensHooke X QC Reticle (For Semen)
- LensHooke X QC Video (For Semen)
- C-KUP Liquefaction Test Cup
- LensHooke Cleaning Wipe CW0 and CW1
- LensHooke Cleaning Wipe Holder CWA

LensHooke CS1 Semen Test Cassette – the same as cleared in K202089
The LensHooke Semen Test Cassette is a microscopic slide for the LensHooke optical analyzer. The LensHooke Semen Test Cassette consists of a top and bottom plastic case and pH paper. There are two windows which analyze concentration, motility and morphology of the semen and the pH of semen respectively.

C-KUP Liquefaction Test Cup – the same as cleared in K202089
The C-KUP Liquefaction Test Cup is used for collection of semen samples, liquefaction, and volume testing. The C-KUP Liquefaction Test Cup is composed of the collection cup, cup cover, and drip cover. The V-Stick in the cup cover is used to check the liquefaction status of the sample. The Scale on the cup is used to determine the volume of the semen sample.

LensHooke X QC Beads (For Semen) – the same as cleared in K202089
LensHooke X QC Beads is the quality control material for semen analysis. The LensHooke X QC Beads (For Semen) are supplied as three different levels of control, and it has been developed as a tool to assess the accuracy and precision of sperm counting and pH test methods by providing a known target value and +/- range.

LensHooke X QC Reticle (For Semen) – the same as cleared in K202089
LensHooke X QC Reticle is the quality control material for semen analysis. The LensHooke X QC Reticle (For Semen) are supplied as three different levels of control, and it has been developed as a tool to assess the accuracy and precision of sperm counting method by providing a known target value and +/- range.

LensHooke X QC Video (For Semen)
LensHooke X QC Video (For Semen) is the quality control material for semen analysis. The LensHooke X QC Video (For Semen) are supplied as three different levels of control and it has been developed as a tool to assess the accuracy and precision of sperm scoring method for motility and morphology by providing a known target value and +/- range.

LensHooke Cleaning Wipe CW0
LensHooke Cleaning Wipe is a plastic stick with lens cotton. Using LensHooke Cleaning

Wipe to clean the Test Cassette Insert Slot of LensHooke Semen Quality Analyzer. This is the cleaning and maintenance procedures usually used for microscopic analyzers.

LensHooke Cleaning Wipe CW1 with CWA Cleaning Wipe Holder
LensHooke Cleaning Wipe CW1 is the cleaning material, lens cotton. When using CW1, the accessory CWA, LensHooke Cleaning Wipe Holder, is required for holding the wipe.
Using the LensHooke Cleaning Wipe to clean the Test Cassette Insert Slot of LensHooke Semen Quality Analyzer. This is the cleaning and maintenance procedures usually used for microscopic analyzers.

B Instrument Description Information:

1. Instrument Name:
   LensHooke X3 PRO Semen Quality Analyzer
   LensHooke X3 PRO SE Semen Quality Analyzer

2. Specimen Identification:
   A sample ID and/or patient ID number can be manually entered, or barcode scanned on LensHooke X3 PRO Semen Quality Analyzer.
   A sample ID and/or patient ID number can be manually entered on LensHooke X3 PRO SE Semen Quality Analyzer.
   Up to 20 characters are permitted.

3. Specimen Sampling and Handling:
   The sample should be allowed to liquefy at room temperature for at least 30 minutes before testing. The test can be performed up to 1 hour after sample collection. It is recommended that users allow 2 to 7 days without ejaculating before collecting a semen sample. Condoms and lubricants should not be used when collecting a semen sample. Hands should be washed with soap and water before and after handling the semen sample.

4. Calibration:

   The LensHooke X3 PRO Semen Quality Analyzer and LensHooke X3 PRO SE Semen Quality Analyzer are factory calibrated. User calibration is not required.

5. Quality Control:
   QC materials are LensHooke X QC Beads (For Semen), LensHooke X QC Reticle (For Semen) and LensHooke X QC Video (For Semen). LensHooke X QC Beads (For Semen) examines pH value and concentration, while LensHooke X QC Reticle (For Semen) only examines concentration. LensHooke X QC Video (For Semen) examines motility and morphology.

V Substantial Equivalence Information:

A Predicate Device Name(s):
LensHooke X1 Pro Semen Quality Analyzer

B Predicate 510(k) Number(s):
K202089

C Comparison with Predicate(s):

Device & Predicate Device(s):	K242830		K202089
Device Trade Name	LensHooke X3 PRO Semen Quality Analyzer	LensHooke X3 PRO SE Semen Quality Analyzer	LensHooke X1 PRO Semen Quality Analyzer
General Device Characteristic Similarities			
Technology	Desk-top unit consists of light sources, built-in video microscopy and an internal computer containing algorithms for the assessment of semen parameters.	Same	Same
Intended Use Setting	Clinical laboratories and Point-of-Care	Over the counter	Same
Intended Use	The LensHooke® X3 PRO Semen Quality Analyzer used with LensHooke® Semen Test Cassette is an optical device for human semen analysis which provides direct and calculated measurements for: (1) Sperm concentration (M/mL) (2) Total motility (PR+NP, %) - Progressive motility (%) - Non-Progressive motility (%) - Immotility (%) (3) Sperm morphology (normal forms, %) (4) pH value The LensHooke® X3 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 Clinical	The LensHooke® X3 PRO SE Semen Quality Analyzer used with LensHooke® Semen Test Cassette is an optical device for human semen analysis which provides direct and calculated measurements for: (1) Sperm concentration (M/mL) (2) Total motility (PR+NP, %) - Progressive motility (%) - Non-Progressive motility (%) - Immotility (%) (3) Sperm morphology (normal forms, %) (4) pH value The LensHooke® X3 PRO SE Semen Quality Analyzer does not provide a comprehensive evaluation of a male's fertility status. It is a self-testing diagnostic system	Same

	laboratories and Point-of-Care setting to evaluate male fertility.	intended for human semen analysis of individuals at home to evaluate male fertility.	
Parameters	Sperm concentration (M/mL), Total motility (PR+NP, %), Progressive motility (%), Non-Progressive motility (%), Immotility (%), Sperm morphology (normal forms, %), and pH value	Same	Same
General Device Characteristic Differences			
Transmission interface	HDMI/USB/Ethernet		HDMI/USB
Standard/Guidance Document	WHO 5th and 6th Edition	WHO 5th and 6th Edition	WHO 5th Edition
Compatible Consumable	Semen Test Cassette (CS1)	Semen Test Cassette (CS1)	Semen Test Cassette (CS0, CS1)
Control Material	X QC Beads, X QC Reticle, X QC Video	X QC Beads, X QC Reticle, X QC Video	X QC Beads, X QC Reticle
Sample prep	Liquefaction treatment/ dilution	Liquefaction/ sample cup	Liquefaction/ sample cup

VI Standards/Guidance Documents Referenced:

- ISO 14971 Third Edition 2019-12 – Medical devices - Application of Risk Management to Medical Devices. (General)
- CLSI EP06 Evaluation of the Linearity of Quantitative Measurement Procedures, Second Edition
- CLSI EP05-A3 Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline - Third Edition
- CLSI EP25 Evaluation of Stability of In Vitro Medical Laboratory Test Reagents, Second Edition
- CLSI EP07 Interference Testing in Clinical Chemistry – Third Edition
- IEC 60601-13.2 2020-08 CONSOLIDATED VERSION – Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION – Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests
- IEC 61326-1 Edition 3.0 2020-10– Electrical equipment for measurement control and laboratory use - EMC requirements - Part 1: General requirements
- IEC 61326-2-6 Edition 3.0 2020-10 Electrical equipment for measurement control and laboratory use - EMC requirements – Part 2-6 General requirements

- IEC 60601-1-11 Edition 2.1 2020-07 CONSOLIDATED VERSI – Medical Electrical Equipment - Part 1-11: General Requirements for Basic Safety and Essential Performance

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Repeatability
A repeatability study was carried out over the course of one day by three operators using two LensHooke X3 PRO analyzer/three test cassette lot combinations. Due to the limited stability of semen samples, each "day" in the statistical analysis represents different times of day (e.g. every 20 minute = 1 "day"). Measurements were separated into five separate 20-minute time periods or "days". The study included three replicates per run, and two runs every 20 minute, five times/day (3 operator × 3 replicates (with 3 lots) × 2 runs (with 2 devices) × 5 times/day) for a total 90 data points per each sample level). Three semen concentration/semen motility levels were prepared by removing seminal plasma (for high concentrations) and adding seminal plasma (for low concentrations). Sperm motility was adjusted by adding a glucose solution or removing glucose. Data analyses were performed to provide repeatability, between-run, between-day, between-lot, between-instrument and within-laboratory. Results met the predefined acceptance criteria.

Concentration (M/mL)			Repeatability		Between-Run		Between-Lot		Between-Instrument		Between-Operator		Between-Day		Within-Laboratory	
Sample	N	Mean	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
1	90	8.3	0.4	4.3	0.0	0.0	0.1	0.8	0.0	0.0	0.0	0.2	0.0	0.5	0.4	4.4
2	90	71.8	1.6	2.3	0.0	0.0	0.4	0.6	0.0	0.0	0.0	0.0	0.0	0.0	1.7	2.4
3	90	257.3	4.2	1.6	0.0	0.0	1.4	0.6	0.0	0.0	1.2	0.5	0.5	0.2	4.6	1.8
4	90	69.7	1.4	2.0	0.0	0.0	0.0	0.0	0.0	0.0	0.4	0.5	0.4	0.6	1.5	2.1
5	90	77.4	1.4	1.8	0.0	0.0	0.3	0.4	0.0	0.0	0.0	0.0	0.3	0.4	1.5	1.9
6	90	88.5	2.3	2.6	0.0	0.0	0.7	0.8	0.0	0.0	0.7	0.8	0.3	0.4	2.5	2.8
7	90	91.7	1.6	1.8	0.6	0.7	0.2	0.3	0.5	0.5	0.0	0.0	0.0	0.0	1.8	2.0

Total motility (%)			Repeatability		Between-Run		Between-Operator		Between-Instrument		Between-Lot		Between-Day		Within-Laboratory	
Sample	N	Mean	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
1	90	82.6	2.6	3.1	0.2	0.2	0.0	0.0	0.6	0.7	0.2	0.3	0.0	0.0	2.6	3.2
2	90	5.0	0.3	6.7	0.1	1.6	0.2	3.1	0.1	2.2	0.0	0.0	0.1	1.7	0.4	8.1
3	90	87.5	4.0	4.6	0.0	0.0	0.0	0.0	0.6	0.7	0.0	0.0	0.0	0.8	4.1	4.7
4	90	42.5	1.5	3.5	0.2	0.5	0.0	0.0	0.3	0.6	0.0	0.0	0.0	0.0	1.5	3.6
5	90	72.3	3.0	4.1	0.5	0.7	0.6	0.8	0.0	0.0	1.1	1.5	0.0	0.0	3.3	4.5
6	90	67.5	1.8	2.6	0.3	0.5	0.0	0.0	0.6	0.9	0.0	0.0	0.0	0.4	1.9	2.8
7	90	73.7	2.1	2.9	0.0	0.0	0.4	0.5	0.0	0.0	0.9	1.3	0.0	0.7	2.4	3.2

Progressive motility (%)			Repeatability		Between-Run		Between-Operator		Between-Instrument		Between-Lot		Between-Day		Within-Laboratory	
Sample	N	Mean	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%

1	90	72.1	2.2	3.1	0.4	0.6	0.0	0.0	0.4	0.6	0.2	0.3	0.0	0.0	2.3	3.2
2	90	4.9	0.3	7.2	0.1	2.0	0.1	2.1	0.1	2.5	0.0	0.0	0.0	0.0	0.5	9.4
3	90	77.7	3.6	4.6	0.0	0.0	0.4	0.5	0.0	0.0	0.0	0.0	0.6	0.8	3.7	4.7
4	90	39.0	1.4	3.6	0.0	0.0	0.0	0.0	0.3	0.8	0.0	0.0	0.2	0.6	1.5	3.7
5	90	66.3	2.7	4.1	0.2	0.3	0.6	0.9	0.0	0.0	1.0	1.6	0.0	0.0	3.0	4.5
6	90	56.0	1.4	2.5	0.2	0.4	0.0	0.0	0.6	1.1	0.0	0.0	0.6	1.0	1.7	3.0
7	90	60.3	1.7	2.9	0.0	0.0	0.4	0.6	0.0	0.0	0.8	1.4	0.5	0.8	2.0	3.3

Morphology (%)			Repeatability		Between-Run		Between-Operator		Between-Instrument		Between-Lot		Between-Day		Within-Laboratory	
Sample	N	Mean	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
1	90	13.4	0.5	3.8	0.0	0.0	0.0	0.0	0.1	0.6	0.0	0.0	0.0	0.0	0.5	3.9
2	90	3.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
3	90	10.5	0.5	4.7	0.1	1.4	0.0	0.0	0.0	0.0	0.1	1.1	0.0	0.0	0.5	5.1
4	90	9.5	0.5	4.8	0.3	2.7	0.1	0.6	0.0	0.0	0.0	0.0	0.0	0.0	0.5	5.5
5	90	9.6	0.5	5.3	0.0	0.0	0.0	0.0	0.1	0.6	0.0	0.0	0.0	0.3	0.5	5.3
6	90	7.9	0.6	7.1	0.2	2.1	0.0	0.0	0.2	2.9	0.0	0.0	0.1	1.9	0.6	8.1
7	90	14.4	0.5	3.4	0.0	0.0	0.1	0.4	0.0	0.0	0.1	0.0	0.1	0.9	0.5	3.5

Non Progressive Motility (%)			Repeatability		Between-Run		Between-Operator		Between-Instrument		Between-Lot		Between-Day		Within-Laboratory	
Sample	N	Mean	SD	CV %	SD	CV %	SD	CV %	SD	CV %	SD	CV %	SD	CV %	SD	CV %
1	90	10.5	1.1	10.2	0.0	0.0	0.0	0.0	0.0	0.0	0.1	1.1	1.1	10.4	1.5	14.6
2	90	0.2	0.3	NA	0.2	NA	0.0	0.0	0.1	NA	0.0	0.0	0.4	NA	0.6	NA
3	90	9.8	1.4	14.2	0.3	3.0	0.0	0.0	0.4	4.0	0.0	0.0	1.4	14.7	2.1	21.1
4	90	3.5	0.5	13.8	0.2	6.6	0.2	4.8	0.0	0.0	0.0	0.0	0.5	15.3	0.8	22.2
5	90	6.0	0.8	13.6	0.2	2.7	0.0	0.0	0.1	1.2	0.0	0.0	0.8	13.8	1.2	19.6
6	90	11.5	1.1	9.8	0.2	1.7	0.1	0.6	0.0	0.0	0.0	0.0	1.1	9.9	1.6	14.0
7	90	13.4	1.1	8.0	0.3	2.2	0.0	0.0	0.0	0.0	0.0	0.0	1.1	8.3	1.6	11.8

Immotility (%)			Repeatability		Between-Run		Between-Operator		Between-Instrument		Between-Lot		Between-Day		Within-Laboratory	
Sample	N	Mean	SD	CV %	SD	CV %	SD	CV %	SD	CV %	SD	CV %	SD	CV %	SD	CV %
1	90	17.4	2.6	14.7	0.2	0.9	0.0	0.0	0.6	3.3	0.2	1.4	2.6	14.7	3.7	21.1
2	90	95.0	0.3	0.3	0.1	0.1	0.1	0.1	0.1	0.1	0.0	0.0	0.3	0.4	0.5	0.5
3	90	12.5	4.0	32.1	0.0	0.0	0.0	0.0	0.6	4.6	0.0	0.0	4.1	32.5	5.8	45.9
4	90	57.5	1.5	2.6	0.2	0.4	0.0	0.0	0.3	0.5	0.0	0.0	1.5	2.6	2.2	3.7
5	90	27.7	3.0	10.7	0.5	1.8	0.6	2.1	0.0	0.0	1.1	3.9	3.0	10.9	4.4	16.0
6	90	32.5	1.8	5.4	0.3	1.1	0.0	0.0	0.6	2.0	0.0	0.0	1.8	5.6	2.6	8.1
7	90	26.3	2.1	8.1	0.0	0.0	0.4	1.5	0.0	0.0	0.9	3.6	2.2	8.3	3.2	12.2

A separated repeatability study was conducted to evaluate the precision of the pH on the LensHooke X3 PRO Semen Analysis System . The test was performed in one day at one site by three operators using two analyzer/three test cassette lot combinations. Due to the limited stability of semen samples, each “day” in the statistical analysis represents different times of day (every 20 minute = 1 “day”). Measurements were separated into five separate 20-minute time periods or “days”. The study includes three replicates per run, and two runs for every 20 minute, five times/day (3 operator × 3 replicates (with 3 lots) × 2 runs (with 2 devices) × 5 times/day = 90 data points per semen plasma pH value level). Results for pH met the predefined acceptance criteria.

pH			Repeatability		Between-Run		Between-Operator		Between-Instrument		Between-Lot		Between-Day		Within-Laboratory	
Sample	N	Mean	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
Low	90	6.2	0.1	1.4	0.0	0.0	0	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.09	1.5
Normal	90	7.0	0.1	1.8	0.0	0.2	0	0.3	0.0	0.3	0.0	0.3	0.0	0.0	0.13	1.9
High	90	7.8	0.0	0.6	0.0	0.2	0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.05	0.7

Reproducibility

To evaluate the reproducibility of the LensHooke X3 PRO Semen Quality Analyzer, a precision study was conducted using a total of three test cassette lots and two analyzers at three clinical laboratory sites. Three levels of control materials (prepared by LensHooke X QC Beads) were included in the study. For each site, the study was conducted by one operator using two devices and three cassette lots for five days, generating six replicates for each sample. Repeatability, between-day, between-site, between-lot and reproducibility were evaluated. All results met the predefined acceptance criteria.

Parameter	Test level	Mean	Repeatability		Between-Day		Between-Site		Between-Lot		Reproducibility	
			SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
Concentration (M/mL)	Negative	0.00	0.00	NA	0.00	NA	0.00	NA	0.00	NA	0.00	NA
	Level 1	25.45	0.42	1.6	0.08	0.0	0.05	0.2	0.09	0.0	0.43	1.7
	Level 2	50.55	0.67	1.3	0.08	0.0	0.00	0.0	0.07	0.0	0.73	1.4

For pH, three pH levels (labeled #Low, Normal, High) were prepared by adjusting the pH value of the LensHooke X QC Beads control solution for evaluation. For each site, the study was conducted by one operator using two devices and three cassette lots for five days, generating six replicates per sample. A total of three sites performed the evaluation over five days. All results met the predefined acceptance criteria.

Parameter	Test level	Mean	Repeatability		Between-Day		Between-Site		Between-Lot		Reproducibility	
			SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
pH	Low	6.21	0.05	0.7	0.00	0.0	0.00	0.0	0.00	0.0	0.05	0.7
	Normal	7.01	0.04	0.6	0.00	0.0	0.00	0.0	0.00	0.0	0.04	0.6
	High	7.81	0.04	0.5	0.00	0.0	0.00	0.0	0.00	0.0	0.04	0.5

2. Linearity:

Linearity for sperm concentration was evaluated using one analyzer (LensHooke X3 PRO Semen Quality Analyzer) and three cassette lots. Semen samples were prepared at 11 sperm concentrations. Testing was performed in seven replicates per lot per concentration level.

Linearity for sperm pH was evaluated using one analyzer (LensHooke X3 PRO Semen Quality Analyzer) and three cassette lots. Semen samples were taken from volunteers and prepared using sodium phosphate monobasic and sodium phosphate dibasic to create 11 pH intervals. Testing was performed in seven replicates per lot per pH level.

The results demonstrate the linearity for sperm concentration as 0–400 M/mL and sperm pH as 5.8–8.2.

3. Analytical Specificity/Interference:
The potential interference of various substances on LensHooke X3 PRO concentration results were evaluated by using two sperm concentration levels (50–100 M/mL and 100–200 M/mL). The following 11 interfering substances were tested in the study: vitamin B, testosterone, yeast, E. Coli, RBC, WBC, urine, saliva, D- norgestrel, and β-estradiol. Samples were tested in five replicates on one analyzer using three lots of test cassettes. Results of test group were compared to the control group. Study results showed that no significant interference was caused by the substances to the tested concentration as described in the table below and sperm concentration was not impacted by agglutination.

Interferent	Tested concentration with no interference
Vitamin B	700 ng/L
Testosterone	1200 ng/dL
Yeast	9.8 x10^7 CFU/mL
E. coli	5 x10^7 /mL
RBC	6.1 x 10^6 /mL
WBC	5 x 10^6 /mL
Urine	5%
Saliva	5%
D-norgestrel	50 ng/mL
B-estradiol	800 pg/mL

4. Assay Reportable Range:
Semen concentration: 2–300 (M/mL)
Total motility: 1–100%
Progressive motility: 1–100%
Non-progressive motility: 1–100%
Immotility: 1–100%
Morphology: 1–100%
pH: 6.0–8.0 (Each Scale Range: 0.2)

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

Sample stability
Sample stability was performed to support the recommended storage and handling instructions found in the device labeling. Native semen samples at three levels of each parameter (concentration, pH, motility and morphology) were assessed at five time points (i.e., 0, 50, 70, 90 and 150 min) at room temperature (25±5℃) with three reagent lots, three replicates per each semen sample. The study data demonstrated that semen is stable at room temperature (25±5℃) for 60 mins.

6. Detection Limit:
A study was conducted to determine the detection limits of the LensHooke X3 PRO Semen Quality Analyzer. Blank and low measurand level samples were prepared from semen samples taken from volunteers. Blank samples were prepared by centrifuging native semen samples to obtain sperm-free seminal plasma as verified by manual microscope. Low

measurand level samples were prepared by diluting native semen samples with sperm-free seminal plasma to a concentration of 0–5 M/mL as verified by manual microscope. Blank and low-level samples were divided into four aliquots and tested in five replicates once a day for three days, using two lots of test cassettes and two analyzers. Results were calculated, and the detection limits were determined to be:

Limit of Blank (LoB) = 0 M/mL
Limit of Detection (LoD) = 0.06 M/mL
Limit of Quantitation (LoQ) = 0.09 M/mL

7. Assay Cut-Off:
   Not applicable.

8. Accuracy (Instrument):
   Please see section "Comparison Studies: Method comparison study".

9. Carry-Over:
   Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   A method comparison study was conducted to demonstrate test performance of the LensHooke X3 PRO SE Semen Quality Analyzer comparing to the predicate. The study was performed by recruiting a total of 166 lay users. The collected samples were first evaluated by lay users (including 42 females testing provided semen samples) on the LensHooke X3 PRO SE Semen Quality Analyzer. The same samples were subsequently assessed by a point-of-care (POC) operator on the same LensHooke X3 PRO SE Semen Quality Analyzer and a technologist on the LensHooke X1 PRO Semen Quality Analyzer. Six POC operators were included in the study with three LensHooke X3 PRO SE Semen Quality Analyzers. Three-way data analysis was performed, and the results are summarized in the following tables. All results met the predefined acceptance criteria.

   LensHooke X3 PRO SE Semen Quality Analyzer (OTC users) vs. LensHooke X1 PRO Semen Quality Analyzer

Parameter	N	Result Range	Slope (95% CI)	Intercept (95% CI)	R^2
Concentration (M/mL)	166	8.4 to 288.7	1.00 (0.97, 1.02)	-1.58 (-3.09, 0.44)	0.99
Total Motility (%)	166	1 to 93	1.03 (1.00, 1.06)	-1.41 (-2.75, -1.00)	0.98
Progressive Motility (%)	166	1 to 92	1.04 (1.01, 1.08)	-0.54 (-1.32, 0.35)	0.98
Morphology (%)	166	1 to 13	1.00 (1.00, 1.00)	0.00 (0.00, 0.00)	0.97
Non-progressive Motility (%)	166	0 to 35	1.00 (1.0, 1.13)	-1.00 (-1.63, -1.00)	0.61
Immotility (%)	166	7 to 98	1.03 (1.00, 1.07)	-1.72 (-4.07, 1.00)	0.98
pH	166	7.2 to 8.0	1.00 (1.00, 1.00)	0.00 (0.00 - 0.00)	0.99

   LensHooke X3 PRO SE Semen Quality Analyzer (POC operators) vs. LensHooke X1 PRO Semen Quality Analyzer

Parameter	N	Result Range	Slope (95% CI)	Intercept (95% CI)	R^2
Concentration (M/mL)	166	8.9 to 294.6	0.99 (0.97, 1.03)	-1.33 (-2.40, -0.12)	0.99
Total Motility (%)	166	1 to 93	1.03 (1.00, 1.06)	-0.50 (-2.94, 1.00)	0.98

Parameter	N	Result Range	Slope (95% CI)	Intercept (95% CI)	R^2
Progressive Motility (%)	166	1 to 92	1.05 (1.02, 1.08)	-0.26 (1.02, 1.08)	0.98
Morphology (%)	166	1 to 13	1.00 (1.00, 1.00)	0.00 (0.00, 0.00)	0.98
Non-progressive Motility (%)	166	0 to 35	1.00 (0.88, 1.19)	0.50 (-1.13, 1.47)	0.87
Immotility (%)	166	7 to 98	1.00 (0.96, 1.09)	-1.00 (-5.54, -1.22)	0.99
pH	166	7.2 to 8.0	1.00 (1.00, 1.00)	0.00 (0.00, 0.00)	0.98

LensHooke X3 PRO SE Semen Quality Analyzer (OTC users vs. POC operators)

Parameter	N	Result Range	Slope (95% CI)	Intercept (95% CI)	R^2
Concentration (M/mL)	166	8.4 to 294.6	1.00 (0.97, 1.03)	-2.87 (-4.48, -1.20)	0.99
Total Motility (%)	166	1 to 93	1.00 (0.97, 1.04)	0.00 (-2.06, 1.01)	0.98
Progressive Motility (%)	166	1 to 92	1.00 (0.97, 1.03)	0.00 (-1.28, 0.81)	0.98
Morphology (%)	166	1 to 13	1.00 (1.00, 1.00)	0.00 (0.00, 0.00)	0.96
Non-progressive Motility (%)	166	0 to 35	1.00 (0.93, 1.00)	0.00 (0.00, 0.37)	0.90
Immotility (%)	166	7 to 98	1.00 (0.98, 1.04)	0.00 (-2.39, 1.26)	0.98
pH	166	7.2 to 8.0	1.00 (1.00, 1.00)	0.00 (0.00, 0.00)	0.99

2. Matrix Comparison:

To support using diluted or liquefaction treated samples on LensHooke X3 PRO Semen Quality Analyzer, a matrix comparison study was conducted on seminal plasma diluted with SpermRinse (K000621) and LifeGlobal HTF Total (K112083), or treated with QwikCheck Liquefaction kit. For dilution treatment, fresh semen samples with varying sperm concentrations (0–20 M/mL, 21–50 M/mL and 51–100 M/mL) were diluted 2x and 4x with either diluent medium. Each sample was tested in three replicates using one analyzer and three lots of test cassettes. Results were compared to the fresh samples diluted 2x and 4x with seminal plasma.

For liquefaction treatment, the fresh semen samples with varying sperm concentrations (0–20 M/mL, 21–50 M/mL and 51–100 M/mL) were treated with liquefaction enzyme in the QwikCheck Liquefaction kit. Each sample was tested in three replicates using one analyzer and three lots of test cassettes. Results were compared to the fresh sample liquefied 30 minutes at room temperature without any treatment.

Additional repeatability studies were performed for diluted and liquefaction treated semen samples. A separate study evaluating the performance between LensHooke X3 PRO Semen Quality Analyzer and manual microscope with diluted and liquefaction treated semen samples was performed by assessing 10 samples. All study results support the use of SpermRinse and LifeGlobal HTF Total as diluents, or treatment with QwikCheck Liquefaction kit on LensHooke X3 PRO Semen Quality Analyzer.

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:

The lower limit of the reference range for parameters Sperm Concentration (M/mL), Total Motility (%), Progressive Motility (%), Non-progressive Motility (%), Immotility (%) and Morphology (%) 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).

F Other Supportive Instrument Performance Characteristics Data:

Sample Volume
A specimen volume study was performed to determine the minimum sample volume at which consistent and accurate results would be obtained on the LensHooke X3 PRO and LensHooke X3 PRO SE Semen Quality Analyzers with LensHooke Semen Test Cassette. Semen samples with low and high concentrations were used to evaluate sample volumes of 35, 40 and 45 µL. Testing was performed in five replicates, using three lots of test cassettes, and the results were compared to predicate device, the LensHooke X1 PRO analyzer. The study results demonstrated that measurements were consistent regardless of specimen volume when the volume ranged from 35 to 45 µL. The minimum sample volume required for testing semen parameters on the LensHooke Semen Test Cassette was determined to be 35 µL.

To determine the minimum sample volume for pH testing, a semen sample at pH 7.8 was used to evaluate sample volumes of 30, 40, 50, 60, 70 and 80 µL. Testing was performed in three replicates per analyzer, with six replicates in total for three lots of test cassettes. The results were compared to the reference pH meter. The study demonstrated that measurements were consistent regardless of specimen volume when the volume ranged from 30 to 80 µL. The minimum sample volume for testing pH on the LensHooke analyzers was determined to be 30 µL.

Operated Temperature and Humidity
The operated temperature and humidity effect study was evaluated under various environment factors: 15 and 38°C (59 and 100°F) and each with 50% and 90% relative humidity. The study was conducted using six levels of semen samples with three replicates per sample, using one analyzer and three lots of test cassettes. The results were compared against LensHooke X1 PRO Analyzer.

Separate operated temperature and humidity effect study were conducted for pH under various environment factors: 15, 25 and 38°C (59, 77 and 100°F) and 50–90% relative humidity. The study was conducted with three pH levels of semen samples with five replicates per sample,

using one analyzer and three lots of test cassettes. The results were compared against the reference method pH meter.

The study results demonstrate the operated temperature and humidity ranges for LensHooke X3 PRO and LensHooke X3 PRO SE Semen Quality Analyzers are 15–38°C (59–100°F) and 50–90% relative humidity, respectively.

Cleaning, Disinfection and Robustness
The cleaning and disinfection study was performed to evaluate the robustness of the LensHooke X3 PRO Semen Quality Analyzer using CaviWipes disinfecting towelettes. Two wipe cycles were used per test process following the instructions: one wipe for cleaning and one wipe for disinfection. Accuracy of the LensHooke X3 PRO analyzer was assessed before cleaning/disinfecting and after simulated use cleaning/disinfecting conditions for the expected 5-year lifetime of the meter. Simulated use is estimated to be 18,240 times (10 times per day × 365 days × 5 years). Study results support acceptable performance of LensHooke X3 PRO Semen Quality Analyzer for the 5-year lifetime claim.

Virucidal Efficacy
A disinfection efficacy validation study was performed to evaluate the disinfectant used to clean and disinfect the exterior surface of the LensHooke device against duck Hepatitis B Virus (dHBV). The study was performed using CaviWipes disinfecting towelettes on different material types of the LensHooke devices, including Polycarbonate + Acrylonitrile Butadiene Styrene (PC+ABS), Polyamide (PA), Glass, and Chloroprene rubber (CR). Clinical serum (DHBsAG) was evaluated for virus recovery control, neutralizer effectiveness/viral interference control, cytotoxicity control, cell viability control, and virus stock titer control.

The disinfection efficacy study results demonstrate that CaviWipes disinfecting towelettes is effective in removing duck Hepatitis B Virus from the subject devices, supporting the virucidal and disinfection procedure.

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.