Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
www.fda.gov

510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I 510(k) Number:

K180343

II Applicant:

Bonraybio Co., Ltd.

III Proprietary and Established Names:

LensHooke X1 Pro Semen Quality Analyzer, LensHooke X1 Semen Quality Analyzer

IV Regulatory Information:

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

V Submission/Device Overview:

A Purpose for Submission:

Clearance of a new device

B Type of Test:

Semen Analysis: sperm concentration, total motility, sperm morphology, and semen pH

VI Intended Use/Indications for Use:

A Intended Use(s):

Same as Indications for Use

B Indication(s) for Use:

LensHooke X1 Semen Quality Analyzer

The LensHooke X1 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:

- Sperm concentration (10^6 per ml)
- Total motility (PR+NP, %)
- Sperm morphology (normal forms, %)
- pH value

The LensHooke X1 Semen Quality Analyzer does not provide a comprehensive evaluation of a male's fertility status. It is a self-testing, in vitro diagnostic system intended for human semen analysis of individuals at home to evaluate male fertility. The systems are intended for single person use only and should not be shared.

LensHooke X1 PRO Semen Quality Analyzer

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 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.

C Special Conditions for Use Statement(s):

Rx and OTC

The LensHooke X1 Semen Quality Analyzer is intended for over-the-counter (OTC) use. The LensHooke X1 PRO Semen Quality Analyzer is intended for prescription use.

VII Device Description:

A Device Description:

The LensHooke X1 and X1 PRO Semen Quality Analyzer integrates 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, and 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.

Consumables and Components

The LensHooke X1 and X1 PRO Semen Quality System consists of the following components:

- LensHooke X1 Semen Quality Analyzer
- LensHooke Semen Test Cassette
- C-KUP Liquefaction Test Cup
- LensHooke Cleaning Wipe

LensHooke Semen Test Cassette
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 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 Cleaning Wipe
The LensHooke Cleaning Wipe is a plastic stick with a lens cotton tip. The LensHooke Cleaning Wipe is used to clean the Test Cassette Insert Slot of LensHooke Semen Quality Analyzer.

B Instrument Description Information:

Modes of Operation	Yes	No
Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?	☒	☐
Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?	☒	☐
Software		
FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:	☒	☐

1. Instrument Name:

LensHooke X1 Semen Quality Analyzer and LensHooke X1 PRO Semen Quality Analyzer

2. Specimen Identification:

   A patient ID number can be manually entered on both the LensHooke X1 and X1 PRO Semen Quality Analyzer. Up to 15 characters are permitted.

3. Specimen Sampling and Handling:

   The semen sample should be collected in the C-KUP Liquefaction Test Cup provided with the kit. 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 X1/X1 PRO Semen Quality Analyzer is factory calibrated. User calibration is not required.

5. Quality Control:

   Quality control for the LensHooke is performed as an internal system check in which a semen test cassette is inserted into the device (without sample) and tested. The QC procedure without sample simulates the testing condition which the sample windows on the test cassette are captured through the camera module and analyzed by software/firmware to ensure the system is working properly. External QC material (i.e. beads for sperm concentration and/or videos for motility, morphology) will be provided for users of the LensHooke X1 and X1 PRO upon request by contacting customer service.

VIII Substantial Equivalence Information:

A Predicate Device Name(s):

SQA-V, Sperm Quality Analyzer

B Predicate 510(k) Number(s):

K021746

C Comparison with Predicate:

Device & Predicate Device(s):	LensHooke X1 PRO Semen Quality Analyzer (Professional) K180343	LensHooke X1 Semen Quality Analyzer (OTC) K180343	SQA-V, Sperm Quality Analyzer – Visual K021746
Similarities			
Intended Use/Indications For Use	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 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.	The LensHooke X1 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: - Sperm concentration (10^6 per ml) - Total motility (PR+NP, %) - Sperm morphology (normal forms, %) - pH value The LensHooke X1 Semen Quality Analyzer does not provide a comprehensive evaluation of a male's fertility status. It is a self-testing, in vitro diagnostic system intended for human semen analysis of individuals at home to evaluate male fertility. The systems are intended for single person use only and should not be shared.	The SQA V is a point-of-care, electro-optical device with on-screen visualization that is used for semen analysis. The SQA V reports: • 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 (FSC, millions/mL)
Sample Type	Human Semen	Human Semen	Human Semen
Parameters	Sperm Concentration, motility, morphology	Sperm Concentration, motility, morphology	Sperm concentration, motility, morphology
Test Type	Quantitative	Quantitative	Quantitative

Device & Predicate Device(s):	LensHooke X1 PRO Semen Quality Analyzer (Professional) K180343	LensHooke X1 Semen Quality Analyzer (OTC) K180343	SQA-V, Sperm Quality Analyzer – Visual K021746
Similarities			
Test Principle	Optical design and Image processing method Image analysis	Optical design and Image processing method Image analysis	Optical absorption and light scatter
Differences			
Standard/ Guidance Document	WHO 5th edition guidelines	WHO 5th edition guidelines	WHO 4th edition guidelines
Parameters	Semen pH	Semen pH	N/A
Test Locale	POC	Home Use	POC
Transmission Interface	HDMI/USB	Bluetooth/Wi-Fi	N/A

IX Standards/Guidance Documents Referenced:

1. ISO 14971 – Medical devices - Application of Risk Management to Medical Devices. (General)

2. IEC 60601-1:2005 – Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

3. IEC 60601-1-2 – Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests

4. IEC 60601-1-11 – Medical Electrical Equipment - Part 1-11: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in The Home Healthcare Environment

5. IEC 61000-3-2 – Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (Equipment input current $\leq$ 16 A per phase)

6. IEC 61000-3-3 – Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current $\leq$ 16 A per phase and not subject to conditional connection

7. World Health Organization. (2010). *WHO Laboratory Manual for The Examination and Processing of Human Semen, 5th Ed.* Geneva: WHO Press

X Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Repeatability

A precision study was carried out over the course of one day by three operators using three analyzer/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 4 hours = 1 "day"). Measurements were separated into five separate 4-hour time periods or "days". The study included two replicates per run, and two runs every 4 hours, five times/day (3 operator/analyzer/cassette lot combinations × 2 replicates × 2 runs × 5 "days") for a total of 60 replicates per sperm concentration/sperm motility/sperm morphology level. Seven semen samples with the following combinations of sperm concentration, motility, and morphology levels were evaluated:

	Conc. M/mL	Motility %	Morphology %
Low	Sample 1/ 5-10	Sample 2/ <2	Sample 2/ <2
Middle	Sample 2/ 50-100	Sample 4/ 30-50	Sample 6/ 3-8
High	Sample 3/ 200-300	Sample 5/ 51-80	Sample 7/ 9-20

Results for concentration, motility and morphology met the predefined acceptance criteria.

Concentration			Within-Run		Between-Run		Between-Day		Between-Operator/Lot/Instrument (SD, %CV)		Total	
Sample	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	60	8.1	0.77	9.4	0.51	6.2	0.49	6.0	0.74	9.1	0.61	7.5
2	60	68.6	6.56	9.6	4.46	6.5	2.45	3.6	5.32	7.8	4.13	6.0
3	60	248.6	23.03	9.3	15.49	6.2	10.27	4.1	19.58	7.9	15.46	6.2
4	60	56.6	5.40	9.5	3.72	6.6	2.32	4.1	4.51	8.0	3.54	6.3
5	60	75.3	5.35	7.1	3.45	4.6	2.34	3.1	4.58	6.1	3.63	4.8
6	60	57.7	4.54	7.9	2.93	5.1	3.63	6.3	4.94	8.5	4.15	7.2
7	60	54.2	4.16	7.7	2.72	5.0	3.01	5.5	4.28	7.9	3.57	6.6

*Every 4-hour run = one testing day

Motility			Within-Run		Between-Run		Between-Day		Between-Operator/Lot/Instrument (SD, %CV)		Total	
Sample	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	60	8.1	0.81	9.9	0.55	6.7	0.36	4.4	0.68	8.4	0.54	6.6
2	60	0.0	0.00	0.0	0.00	0.0	0.00	0.0	0.00	0.0	0.00	0.0
3	60	0.0	0.00	0.0	0.00	0.0	0.00	0.0	0.00	0.0	0.00	0.0
4	60	47.1	4.2	9.0	2.67	5.7	3.44	7.3	4.65	9.9	3.9	8.3
5	60	6.75	4.57	6.8	3.11	4.6	5.80	8.6	6.67	9.9	5.84	8.7
6	60	43.4	4.18	9.6	2.77	6.4	3.07	7.1	4.32	10.0	3.60	8.3
7	60	62.3	6.09	9.8	4.28	6.9	4.24	6.8	6.05	9.7	5.00	8.0

*Every 4-hour run = one testing day

Morphology			Within-Run		Between-Run		Between-Day		Between-Operator/Lot/Instrument (SD, %CV)		Total	
Sample	N	Mean	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
1	60	7.8	0.73	9.4	0.48	6.1	0.42	5.4	0.68	8.8	0.55	7.1
2	60	0.0	0.00	0.0	0.00	0.0	0.00	0.0	0.00	0.0	0.00	0.0
3	60	0.0	0.00	0.0	0.00	0.0	0.00	0.0	0.00	0.0	0.00	0.0
4	60	11.2	1.1	10.0	0.72	6.5	0.43	3.8	0.92	8.3	0.72	6.5
5	60	9.4	0.89	9.4	0.57	6.0	0.23	2.4	0.69	7.3	0.53	5.6
6	60	7.5	0.34	4.6	0.23	3.0	0.32	4.3	0.41	5.4	0.35	4.7
7	60	16.0	1.41	8.8	0.91	5.7	0.57	3.5	1.18	7.4	0.92	5.8

Every 4-hour run = one testing day

A separate repeatability study was conducted to evaluate the precision of the pH parameter on the LensHooke device. The test was performed in one day at one site using three lots of test cassettes and two LensHooke analyzers. Semen samples were prepared at six pH values spread across the measuring range: 6.0, 6.5, 7.0, 7.2, 7.8, and 8.0, verified by pH meter (reference). Each sample was tested in 10 replicates for each of three lots on two LensHooke analyzers. Results for pH met the predefined acceptance criteria.

Reproducibility

To evaluate the reproducibility performance of the LensHooke X1 Semen Quality Analyzer, a precision study was conducted using a total of three cassette lots and three analyzers at three point-of-care (POC) sites in Taiwan representative of POC sites in the U.S., including POC operator equivalency (i.e. job title/position, education, experience, training). Three levels of control solution (prepared latex beads concentration and pH levels (Low, Normal, and High)) were tested in five replicates once per day for five days by one operator on one analyzer using one cassette lot at each site as illustrated in the table below:

Control Level	Sperm Concentration (10^6/mL)	pH	Replication per sample	Days
Low	0	6.2	5	5
Normal	19−31	7.0	5	5
High	43−58	7.8	5	5

For concentration and pH parameters and for each level of control tested, the mean, SD and %CV of the various components of precision were calculated along with the %CV for repeatability and reproducibility (total precision). The data were analyzed using two-way nested ANOVA analysis. All results met the predefined acceptance criteria.

Reproducibility for Combined Sites

Parameter [Units]	Control Level	Mean	Repeatability		Between-Day		Between-Laboratory		Reproducibility (Total Precision)	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
Concentration	L1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

Parameter [Units]	Control Level	Mean	Repeatability		Between-Day		Between-Laboratory		Reproducibility (Total Precision)	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
[10^6/µL]	L2	24.7	1.3	5.1	1.4	5.6	1.4	5.6	1.4	5.7
	L3	49.1	3.6	7.3	3.6	7.4	3.7	7.5	3.7	7.5
pH	L1	6.0	0.0	0.0	0.1	0.9	0.1	0.9	0.1	0.9
	L2	7.0	0.1	0.9	0.1	0.9	0.1	0.9	0.1	1.0
	L3	7.8	0.1	0.7	0.1	0.8	0.1	0.9	0.1	0.9

2. Linearity:

Linearity for sperm concentration and semen pH was evaluated using one analyzer and three cassette lots. Semen samples were prepared at nine sperm concentrations ranging from 2–400 × 10^6/mL. Testing was performed in three replicates per lot per concentration level. The linearity study for pH was performed using two analyzers and three cassette lots. Semen samples were taken from volunteers and prepared using sodium phosphate monobasic and sodium phosphate dibasic to create 13 pH intervals ranging from 5.8–8.2. Testing was performed in three replicates per lot per pH level.

The mean and SD of results were calculated. Regression analysis was used to verify the linear range and the polynomial method was employed to evaluate non-linearity. Sperm concentration was demonstrated to be linear from 2–350 × 10^6/mL. Semen pH was demonstrated to be linear from 5.8–8.2.

3. Analytical Specificity/Interference:

The potential interference of various substances on LensHooke X1 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, agglutination of semen sample, D-norgestrel, and β-estradiol. Samples were tested in five replicates on one analyzer using three lots of test cassettes. Results were compared to the SQA-V Analyzer. Study results showed that all tested interfering substances met the acceptance criteria and no significant interference was caused by the tested substances.

4. Accuracy (Instrument):

Method Comparison

A user performance study was conducted to determine test performance of the LensHooke X1 Semen Quality Analyzer when used by unassisted lay users following the instructions in the package insert. The study was performed at three evaluation sites, including one internal site. A total of 100 lay user participants, including 83 males and 17 females, ranging in age from 21-60 years were included in the study.

The study was conducted in two ways: 1) Performance of male lay users providing and testing their own semen specimen; 2) Performance of lay users recruited to test semen specimens provided by a subset of test subjects. Following collection of the specimen by the

study subject, either the study subject or the tester analyzed the sample on the LensHooke X1 Semen Quality Analyzer. After recording the results, a point-of-care (POC) professional at the study site performed semen analysis on the layperson's sample using the LensHooke X1 and the predicate/reference device, the SQA-V. Semen specimens spanning the analytical measuring range of 2−350 × 10^6/mL were analyzed during the study. Results from the user performance study were compared and analyzed as follows: Layperson results vs. REF results, POC results vs. REF results, and Layperson results vs. POC results.

Correlation of LensHooke X1 (OTC) vs. SQA-V – Combined Sites

Parameter [Units]	Slope (95% CI)	Intercept (95% CI)	R^2
Concentration [10^6/mL]	0.98 (0.95, 1.01)	0.97 (-0.14, 3.16)	0.98
Motility [%]	0.98 (0.95, 1.01)	0.00 (-1.54, 0.74)	0.95
Morphology [%]	0.78 (0.60, 1.00)	0.00 (0.00, 0.00)	0.73

Correlation of LensHooke X1 (POC) vs. SQA-V – Combined Sites

Parameter [Units]	Slope (95% CI)	Intercept (95% CI)	R^2
Concentration [10^6/mL]	0.98 (0.95, 1.01)	0.00 (-1.54, 0.74)	0.98
Motility [%]	0.96 (0.91, 1.00)	0.00 (0.00, 0.00)	0.94
Morphology [%]	0.86 (0.67, 1.18)	0.00 (0.00, 0.00)	0.75

Correlation of LensHooke X1 (OTC) vs. (POC) – Combined Sites

Parameter [Units]	Slope (95% CI)	Intercept (95% CI)	R^2
Concentration [10^6/mL]	1.0 (0.97, 1.02)	1.0 (0.00, 2.62)	0.98
Motility [%]	0.97 (0.94, 1.04)	0.00 (0.00, 0.00)	0.93
Morphology [%]	1.00 (0.76, 1.22)	0.00 (0.00, 0.00)	0.86

Validation of pH

POC personnel performed the pH study by testing the semen samples used in the method comparison with pH test strips. Results were obtained by visual comparison to the pH color card. The pH strip covered the range of 5.0 to 8.5 with 0.5 intervals. The pH results obtained visually using the pH strip were compared to the pH results obtained from the LensHooke X1 and X1 PRO during the method comparison/user study. All results met the predefined acceptance criteria.

pH Parameter Comparison

Comparison	Slope (95% CI)	Intercept (95% CI)	R^2
LensHooke X1 (OTC) vs. pH Strip	1.00 (0.80, 1.00)	-0.05 (-0.05, 1.6)	0.98
LensHooke X1 (POC) vs. pH Strip	0.80 (0.80, 1.00)	1.6 (-0.05, 1.60)	0.95
LensHooke X1 (OTC) vs. (POC)	1.00 (1.00, 1.00)	0.00 (0.00, 0.00)	0.98

5. Carry-Over:

   Not applicable

B Other Supportive Instrument Performance Characteristics Data:

Detection Limits (LoB/LoD/LoQ)

A study was conducted to determine the detection limits of the LensHooke X1 Semen Quality Analyzer. Semen samples were taken from volunteers and two interval ranges were prepared: sperm-free seminal plasma and low concentration seminal plasma. Semen was centrifuged to obtain sperm-free seminal plasma to a concentration of ~0 M/mL (blank sample) as verified by manual microscope. Low concentration seminal plasma was prepared by diluting semen to a concentration of ~2−8 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) = 1.8 M/mL
Limit of Quantitation (LoQ) = 7.2 M/mL

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 analyzer. Semen samples at low and high concentrations were used to evaluate sample volumes at 35, 40 and 45 µL. Testing was performed in five replicates, using three lots of test cassettes and results were compared to the reference method SQA-V analyzer. Success was determined by calculating the bias of specimen volume effect on concentration, motility, and morphology results. Study results demonstrated that measurements were consistent irrespective of specimen volume when specimen volume is 35−45 µL. The minimum sample volume for testing semen parameters on the LensHooke analyzer was determined to be 35 µL.

To determine the minimum sample volume for pH testing, a semen sample with pH value of 7.8 was used to evaluate samples at 30, 40, 50, 60, 70, and 80 µL. Testing was performed in three replicates, using three lots of test cassettes on two LensHooke analyzers for a total six replicates per sample volume. Results were compared to the pH meter (reference). Success was determined

by calculating the bias of specimen volume effect on pH results. Study results demonstrated that measurements were consistent irrespective of specimen volume when specimen volume is 30−80 μL. The minimum sample volume for testing pH on the LensHooke analyzer was determined to be 30 μL.

Cassette Stability

A stability study was conducted to determine the shelf-life of the LensHooke Semen Test Cassette in real-time (at 2°C and 25°C) and under accelerated conditions (at 40°C). Three semen samples with varying sperm concentrations (<2 M/mL, 20−50 M/mL, 51−100 M/mL) and pH levels (6.2, 7.2, 7.8) were tested in three replicates using one analyzer and three lots of test cassettes. All results were compared against the reference method SQA-V Analyzer. Study results demonstrated test cassette strip performance for 8 months under accelerated (40°C) conditions, equivalent to a 2-year shelf-life at room temperature, and 24 months under real-time conditions (2°C and 25°C). Results support the 2 year shelf-life claim at refrigerated and room temperature conditions.

Cleaning, Disinfection and Robustness

The cleaning and disinfection study was performed to evaluate the robustness of the LensHooke X1 PRO 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 X1 PRO device was assessed before cleaning/disinfecting and after simulated use cleaning/disinfecting conditions for the 3-year lifetime of the meter. Simulated use is estimated to be 10,950 times (10 times per day × 365 days × 3 years). Study results supported the 3-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 PC, Silicone, PE and ABS+PC. 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 demonstrated that CaviWipes disinfecting towelettes was effective in removing duck Hepatitis B Virus from the subject devices, supporting the virucidal and disinfection procedure.

XI Proposed Labeling:

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

XII Conclusion:

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