November 16, 2018

Bonraybio Co., Ltd.
% Feng-Yu Lee
Principal Consultant
Dynamic Biotech Inc. dba IVDD Regulatory Consultant
29222 Rancho Viejo Road, Suite 218
San Juan Capistrano, California 92675

Re: K180343
Trade/Device Name: LensHooke X1 Pro Semen Quality Analyzer, LensHooke X1 Semen Quality Analyzer
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated Differential Cell Counter
Regulatory Class: Class II
Product Code: POV
Dated: January 31, 2018
Received: February 7, 2018

Dear Feng-Yu Lee:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Takeesha Taylor-bell -S

Takeesha Taylor-Bell
Branch Chief
Hematology Branch
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

For

Leonthena Carrington
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k180343

Device Name
LensHooke X1 Semen Quality Analyzer
LensHooke X1 PRO Semen Quality Analyzer
LensHooke Semen Test Cassette

Indications for Use *(Describe)*
LensHooke X1 Semen Quality Analyzer for OTC use

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 for prescription 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 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.

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 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 510(k) number is: k180343

1. Submitter's Identification:

bonraybio Co., Ltd
4F., No.118, Gongye 9th Rd., Dali Dist., Taichung City 41280, Taiwan (R.O.C.)
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c/o IVDD Regulatory Consultant
29222 Rancho Viejo Road, Suite 218
San Juan Capistrano, CA 92675
Contact Person: Feng-Yu Lee
Phone Number: 1-949-218-0929
Fax Number: 1-949-218-0928

Date Summary Prepared: November 16th, 2018

2. Name of the Device:
LensHooke Semen Test Cassette
LensHooke X1 Semen Quality Analyzer
LensHooke X1 PRO Semen Quality Analyzer

3. Common or Usual Name: Semen Analysis Device

Product Code	Classification	Regulation Section	Panel
POV; Semen Analysis Device	Class II	21 CFR 864.5220	Hematology 80

4. Device Description:

Semen Quality Analyzer integrates optical design and image analysis and combined with artificial intelligence image processing method, to fully automated analysis of semen quality including semen pH, sperm concentration and motility. The images are captured and recorded by cameras and with image processing methods, the locations of sperms 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. Through camera, the chromatographic

image of pH is captured and with image saturation and brightness analysis, the level of pH is determined.

Product Information

4.1 For Over-the-Counter Setting:

LensHooke X1 Semen System, consist of the following devices:
LensHooke X1 Semen Quality Analyzer
LensHooke Semen Test Cassette
C-KUP Liquefaction Test Cup
LensHooke Cleaning Wipe

The LensHooke X1 Semen Quality Analyzer and LensHooke Semen Test Cassette are manufactured by bonrayBio.

4.2 For Point-of-Care Professional Setting:

LensHooke X1 PRO Semen System, consist of the following devices:
LensHooke X1 PRO Semen Quality Analyzer and LensHooke Semen Test Cassette.
C-KUP Liquefaction Test Cup
LensHooke Cleaning Wipe

The LensHooke X1 PRO Semen Quality Analyzer and LensHooke Semen Test Cassette are manufactured by Bonraybio.

4.3 Consumables Description

LensHooke Semen Test Cassette

LensHooke Semen Test Cassette is a well-designed microscopic slide for the optical analyzer, LensHooke Semen Quality Analyzer. Top and bottom plastic case and pH paper are the components of LensHooke Semen Test Cassette. There are two polished windows which analyzed concentration, motility and morphology of the semen and the pH of semen respectively.

C-KUP Liquefaction Test Cup

C-KUP Liquefaction Test Cup is used to collecting semen samples to liquefaction and volume testing. Collected semen samples are applicable for semen quality analysis. Cup, cup cover and drip cover are the components of C-KUP Liquefaction Test Cup. The V-Stick on cup cover is used to check the liquefaction's status. The Scale on cup is used to check the volume of the semen sample.

LensHooke Cleaning Wipe

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.

5. Indications for Use:

5.1 For Over-the-Counter Setting:

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 systems 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.

5.2 For Point-of-Care Professional Setting:

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.

6. Predicate Device Information:

LensHooke X1 and X1 PRO Semen Quality Analyzers are substantially equivalent to:

SQA V, Sperm Quality Analyzer – Visual

Device Company: Medical Electronic System, LLC

510(k) Number: k021746

7. Comparison to Predicate Devices:

Product Name	LensHooke X1 PRO Semen Quality Analyzer (Professional)	LensHooke X1 Semen Quality Analyzer (OTC)	Predicate (K021746) SQA-V (MES)
Intended 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 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.	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 systems 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)
Male Fertility Factor	Yes		Yes

Technology	Desk-top unit consists of light sources, built-in video microscopy and an internal computer containing algorithms for the assessment of semen parameters.		Desk-top unit consists of a light source, optical sensors, built-in video microscopy and an internal computer containing algorithms for the assessment of semen parameters.
Transmission interface	HDMI/USB	Bluetooth/Wi-Fi	N/A
Intended User	Point-of-Care professional	Over-the-Counter	Professional

8. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence is as follows:

Verification and validation of test results were evaluated to establish the performance, functionality and reliability of LensHooke X1 Semen Quality Analyzer and LensHooke X1 PRO Semen Quality Analyzer.
The evaluation included Repeatability, Reproducibility, LoB/LoD/LoQ and linearity, interference, sample volume, operating conditions and stability in close vial.

Repeatability
The study was conducted two replicates per run, and two runs for every 4 hours, five times/day (3 operator/analyzer/cassette lot combinations × 2 replicates × 2 runs × 5 times/day = 60 data points per sperm concentration/sperm motility/sperm morphology level).

It was demonstrated that the calculate CV (%) pH, Concentration, Motility and morphology were within 10%.

Reproducibility
The evaluation was estimated by control solutions of 3 prepared latex beads concentration and pH levels (Label #Low, Normal, High). Each sample was tested in 5 replicates by 1 operator per day. 3 lots of test system were used and 1 lot per site.
For motility and morphology, due to the limited stability of semen samples, the “day” of repeatability experiment as different times of the day (every 4 hours = 1 “day”). 3 semen motile and 3 semen morphology levels (Label #Low, Normal, High) spread across the measuring interval were evaluated 3 operator/analyzer/cassette lot combinations × 5 replicate × 5 times/day.
Total 3 POC sites with 5 days/times were performed.

It was demonstrated that the calculate CV (%) pH, Concentration, Motility and morphology were within 10%.

LoB/LoD/LoQ

The limit of blank and detection limits were established by assaying two concentration levels, in 5 replicates, with each of the two lots. The concentration levels were LoB: 0 10^6/mL, LoD: 1.8 10^6/mL, and LoQ: 7.2 10^6/mL.

Linearity and Sensitivity

The linearity and sensitivity study for Semen was performed using one analyzer and 3 lots of Cassettes to evaluate detection range. Semen samples were prepared at 9 semen intervals ranged from low to elevated level (2 to 400 x 10^6/mL).
Test procedures were performed in 3 replicates per lot per concentration level and compared with SQA-V analyzer.
The linearity and sensitivity study for pH was performed using two analyzers and 3 lots of Cassettes to evaluate detection range. Semen samples were prepared at 13 pH intervals ranged from pH 5.8 to 8.2.
Test procedures were performed in 3 replicates per lot per pH level and compared with pH meter.

Analysis of results indicated Semen linear regression between device and reference method shows mean slope above 0.95 and R^2 values above 0.99. The results support the claim that the candidate assay is linear from 2 to 350 x10^6/mL concentrations.
The results support the claim that the pH is linear from pH 5.8 to 8.2.

Interference

The interference study was performed using 2 concentration levels (50-100 and 100-200 x 10^6/mL) of semen samples and 11 interference substances. 1 analyzer and 3 lots of test cassettes were used to perform 5 replicates per lot and compared to reference method SQA- V Analyzer.

The study results indicate that all tested 11 interference substances meet CLSI: EP7-A2 acceptance criteria for therapeutic levels of concentration. Tested substances do not cause significant interference.

Sample Volume

Semen Study

The specimen volume study was performed using 3 lots of test cassette, semen samples at low and high concentrations were used to evaluate sample volumes at 35, 40 and 45 uL. Test procedures were performed in 5 replicates, and results were compared to reference method SQA-V Analyzer.

The study results demonstrate the CV is within 5% and the bias is within 20% for semen concentration. All results within criteria when specimen is 35-45 µL. Thus, the minimum sample volume is 35 µL.

pH Study

The specimen volume study was performed using 3 lots of pH test, semen sample at pH 7.8 was used to evaluate sample volumes at 30, 40, 50, 60, 70 and 80uL. Test procedures

were performed in 3 replicates per analyzer, 6 replicates in total. The results were compared to reference method pH meter.

The study results demonstrate the CV is within 10% and the bias is within 10%. All results within criteria when specimen is 30-80 μL. Thus, the minimum sample volume is 30 μL.

Operated Temperature and Humidity

Semen Study

The operated temperature and humidity effect study was evaluated under various environment factors: 15 and 38°C (59 and 100.4°F) and each with 50% and 90% relative humidity. Six concentration levels of Semen samples, 1 analyzer, and 3 lots of test cassette were used. Test procedures were performed in 5 replicates. The results were compared against reference method SQA-V Analyzer.

The results indicate basis within 10% and conclude that candidate device can operate under the environment conditions 15-38°C (59-100.4°F) and 50-90% relative humidity.

pH Study

The operated temperature and humidity effect study was evaluated under various environment factors: 15, 25 and 38°C (59, 77 and 100.4°F) and 50% to 90% relative humidity. Three pH levels of Semen samples, 1 analyzer, and 3 lots of test cassette were used. Test procedures were performed in 5 replicates. The results were compared against reference pH meter.

The results indicate basis within 10% and conclude that candidate device can operate under the environment conditions 15-38°C (59-100.4°F) and 50-90% relative humidity.

Test Strip Stability (Closed Vial)

The closed vial test stability studies were performed for Semen Test cassette to evaluate the following:

Real-Time Conditions (2 and 25°C)
Accelerated Conditions (40°C)
1 Analyzer, 3 lots of Test Cassette, and 3 Semen samples were used to perform the Semen and pH stability study, test measurements in 3 replicates. All results were compared against reference method SQA-V Analyzer.

The study results should demonstrate stable test cassette strip performance for 8 months under accelerated 40°C condition, which can estimate shelf life of test strips for 2 years at room temperature.

9. Discussion of Clinical Tests Performed:

System Accuracy Study and Layuser Performance Study

The user performance study was performed to demonstrate that English speaking and reading lay users across all educational backgrounds can easily understand and follow the labeling/user instructions to obtain accurate results while using Candidate device. The study was also performed using Point-of-Care professionals or licensed registered nurses to obtain POC test findings.

The evaluation was conducted on 106 subjects with 5 units of candidate device and accompanying user instructions, 100 subjects' findings were tabulated, excluded findings were addressed in the study report. SQA-V Analyzer performed by POC personnel was used as a reference method.

The study results demonstrate that the layperson user accuracy and ease of use (via participant questionnaire scoring) of Candidate device. The study protocol, user questionnaire and form, and study findings are attached for your review.

10. Conclusions:

Results of performance evaluation of LensHooke X1 Semen Quality Analyzer and LensHooke X1 PRO Semen Quality Analyzer demonstrate that the candidate devises are substantial equivalence to the predicate device, SQA V, Sperm Quality Analyzer.