October 28, 2020

Bonraybio Co., Ltd.
% Feng-Yu Lee
Principal Consultant
Dynamic Biotech, Inc dba. IVDD Regulatory Consultant
29122 Rancho Viejo Rd., Suite 212
San Juan Capistrano, California 92675

Re: K202089
Trade/Device Name: LensHooke X1 PRO Semen Quality Analyzer, LensHooke X1 PRO SE Semen Quality Analyzer
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated Differential Cell Counter
Regulatory Class: Class II
Product Code: POV, GKZ
Dated: July 21, 2020
Received: July 28, 2020

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Takeesha Taylor-Bell
Chief
Division of Immunology
and Hematology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202089

Device Name
LensHooke X1 PRO Semen Quality Analyzer

Indications for Use *(Describe)*
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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K202089

Device Name
LensHooke X1 PRO SE Semen Quality Analyzer

Indications for Use *(Describe)*

The LensHooke X1 PRO SE 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 PRO SE 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.

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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PRAStaff@fda.hhs.gov

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510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 510(k) number is:

1 Submitter's Identification:

1.1 BonrayBio Co., Ltd.
4F., No.118, Gongye 9th Rd., Dali Dist., Taichung City 41280, Taiwan(R.O.C)
Contact Person: Clare Huang
TEL: +886-4-24912385
FAX: +886-4-24912885

1.2 c/o IVDD Regulatory Consultant
29122 Rancho Viejo Road, Suite 212, San Juan Capistrano, CA 92675
Contact Person: Feng-Yu Lee
TEL: 1-949-218-0929
FAX: 1-949-218-0928

1.3 Date Summary Prepared: July 17th, 2020

2 Name of the device:

LensHooke Semen Test Cassette
LensHooke X1 PRO Semen Quality Analyzer
LensHooke X1 PRO SE Semen Quality Analyze

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 PRO SE Semen System, consist of the following devices:
LensHooke X1 PRO SE Semen Quality Analyzer
LensHooke Semen Test Cassette
LensHooke X QC Beads (For Semen)
LensHooke X QC Reticle (For Semen)
C-KUP Liquefaction Test Cup
LensHooke Cleaning Wipe

The LensHooke X1 PRO SE 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
LensHooke Semen Test Cassette
LensHooke X QC Beads (For Semen)
LensHooke X QC Reticle (For Semen)
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.

LensHooke X QC Beads (For Semen)

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)

LensHooke X QC Beads 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.

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:

The LensHooke X1 PRO ^{SE} 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 PRO ^{SE} 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.

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 PRO and X1 PRO ^{SE} Semen Quality Analyzer are substantially equivalent to：

LensHooke X1 PRO and X1 Semen Quality Analyzer

Device Company: Bonraybio Co., LTD.

510(k) Number: k180343

7 Comparison to Predicate Device:

7.1 LensHooke X1 PRO Semen Quality Analyzer:

Product Name	LensHooke X1 PRO Semen Quality Analyzer (Candidate Device)	LensHooke X1 PRO Semen Quality Analyzer (Predicate Device)
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.	Same
Male Fertility Factor	Yes	Same
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
Transmission interface	HDMI/USB	Same

Intended User	Point-of-Care professional	Same
Compatible Semen Test Cassette Model	CS0, CS1	CS0
Control Material	X QC Beads, X QC Reticle	Quality control by blank cassette

7.2 LensHooke X1 PRO ^{SE} Semen Quality Analyzer：

Product Name	**LensHooke X1 PRO ^{SE} Semen Quality Analyzer (Candidate Device)**	**LensHooke X1 Semen Quality Analyzer (Predicate Device)**
Intended Use	The LensHooke X1 PRO ^{SE} 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 PRO ^{SE} 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.	Same
Male Fertility Factor	Yes	Same
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
Transmission interface	HDMI/USB	Bluetooth/Wi-Fi
Intended User	Over-the-Counter	Same
Compatible Semen Test Cassette Model	CS0, CS1	CS0
Control Material	X QC Beads, X QC Reticle	Quality control by blank cassette

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 PRO ^{SE} Semen Quality Analyzer and LensHooke X1 PRO Semen Quality Analyzer. The evaluation included Repeatability, Reproducibility, LoB/LoD/LoQ and linearity, sample volume, operating conditions and stability.

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. 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.

10 Conclusions

Results of performance evaluation of LensHooke X1 PRO ^{SE} Semen Quality Analyzer and LensHooke X1 PRO Semen Quality Analyzer demonstrate that the candidate devises are substantial equivalence to the predicate device, LensHooke X1 Semen Quality Analyzer and LensHooke X1 PRO Semen Quality Analyzer.