May 30, 2025

Bonraybio Co., LTD.
Clare Huang
Manager
4F., No. 118, Gongye 9th Rd., Dali Dist.
Taichung, 41280
Taiwan

Re: K242830
Trade/Device Name: LensHooke X3 PRO Semen Quality Analyzer; LensHooke X3 PRO SE Semen Quality Analyzer
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated Differential Cell Counter
Regulatory Class: Class II
Product Code: POV
Dated: September 18, 2024
Received: September 19, 2024

Dear Clare Huang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

MIN WU -S

Min Wu, Ph.D.
Branch Chief
Division of Immunology and Hematology Devices
OHT7: Office of In Vitro Diagnostics
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242830

Device Name
LensHooke X3 PRO SE Semen Quality Analyzer
LensHooke X3 PRO Semen Quality Analyzer

Indications for Use *(Describe)*

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 quantitative 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 quantitative 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 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 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K242830

1 Submitter's Identification:

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

1.2 Date Summary Prepared: May 26th, 2025

2 Name of the device:

LensHooke X3 PRO Semen Quality Analyzer
LensHooke X3 PRO SE 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

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 sperm pH, semen concentration, motility, and morphology. 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 X3 PRO SE Semen System, consist of the following devices:
LensHooke X3 PRO SE 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
LensHooke Cleaning Wipe CW1
LensHooke Cleaning Wipe Holder CWA

The LensHooke X3 PRO SE Semen Quality Analyzer and accessories are manufactured by Bonraybio.

4.2 For Point-of-Care Professional Setting:
LensHooke X3 PRO Semen System, consist of the following devices:
LensHooke X3 PRO 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
LensHooke Cleaning Wipe CW1
LensHooke Cleaning Wipe Holder CWA

The LensHooke X3 PRO Semen Quality Analyzer and accessories are manufactured by Bonraybio.

4.3 Accessories Description
LensHooke CS1 Semen Test Cassette
LensHooke CS1 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 by providing a known target value and +/- range.

LensHooke X QC Reticle (For Semen)
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 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.

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 CW0 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.

LensHooke CW1 Cleaning Wipe and LensHooke CWA Cleaning Wipe Holder

LensHooke CW1 Cleaning Wipe is a lens cotton used with a LensHooke CWA Cleaning Wipe Holder. 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® 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.

5.2 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.

6 Predicate Device Information

LensHooke X3 PRO and X3 PRO SE Semen Quality Analyzer are substantially equivalent to：
LensHooke X1 PRO and X1 PRO SE Semen Quality Analyzer
Device Company: Bonraybio Co., LTD.
510(k) Number: K202089

7 Comparison to Predicate Device:

7.1 LensHooke X3 PRO Semen Quality Analyzer:

Product Name	LensHooke X3 PRO Semen Quality Analyzer (Subject Device)	LensHooke X1 PRO Semen Quality Analyzer (Predicate Device)
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 laboratories and point-of-care setting to evaluate male fertility.	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.
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/Ethernet	HDMI/USB
Intended	Point-of-Care professional	Same

User		
Compatible Consumable	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

7.2 LensHooke X3 PRO SE Semen Quality Analyzer:

Product Name	**LensHooke X3 PRO SE Semen Quality Analyzer (Subject Device)**	**LensHooke X1 PRO SE Semen Quality Analyzer (Predicate Device)**
Intended Use	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.	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: (1) Sperm concentration (10^6 per ml) (2) Total motility (PR+NP, %) (3) Sperm morphology (normal forms, %) (4) pH value The LensHooke X1 PRO SE Semen Quality Analyzer does not provide a comprehensive evaluation of a male's fertility status. It is 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.
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/Ethernet	HDMI/USB
Intended User	Over-the-Counter	Same
Compatible Consumable	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

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 X3 PRO Semen Quality Analyzer and LensHooke X3 PRO SE Semen Quality Analyzer. The evaluation included repeatability, reproducibility, LoB/LoD/LoQ, linearity, interference, matrix comparison, sample volume, operating conditions and stability.

9 Discussion of Clinical Tests Performed

System Accuracy Study and User Performance study

The user performance study was performed to demonstrate that English speaking and reading adult lay users including male and female across different education backgrounds can easily understand and follow the labeling/user instructions to obtain accurate results while using Subject Device. The study was performed using Point-of-Care professionals or licensed registered nurses to obtain POC test findings. LensHooke X1 PRO Semen Quality Analyzer performed by POC personnel was used as reference method. The study results demonstrate that the layperson user accuracy and ease of use (via participant questionnaire scoring) of subject device.

10 Conclusions

Any noted differences do not raise new issues of safety and effectiveness that the benefit outweighs the total and residual risks. Results of performance evaluation of LensHooke X3 PRO Semen Quality Analyzer and LensHooke X3 PRO SE Semen Quality Analyzer demonstrate that the subject devises are substantial equivalence to the predicate device, LensHooke X1 PRO Semen Quality Analyzer and LensHooke X1 PRO SE Semen Quality Analyzer.