April 9, 2026

Checkcells, Inc.
Martin Kosela
CEO & President
1725 Ocean Front Walk Unit 713
Santa Monica, CA 90401 USA

Re: K252228
Trade/Device Name: Seaman PRO
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: POV
Dated: July 16, 2025
Received: July 18, 2025

Dear Martin Kosela:

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.

Please note that if you modify your IVD in the future to exceed any of the limitations to the exemption found in 21 CFR 864.9(c), your device will require a new 510(k) prior to marketing this device in the United States and will not be exempt from the premarket notification requirements so long as it exceeds the limitations to the exemption found in 21 CFR 864.9.

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,

for Ying Mao -S

Takeesha Taylor-Bell
Deputy Director
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)*
K252228

Device Name
Seaman PRO

Indications for Use *(Describe)*
The Seaman PRO Analyzer is an automated, point-of-care, in vitro use-only medical device for semen analysis performed by healthcare professionals. The desktop unit consists of a light source, optical elements, and an image sensor connected to a PC, which records a video of the semen sample and sends it to the cloud compute unit. The cloud compute unit runs software containing algorithms for assessing semen parameters. The product is a software-based medical device powered by ML that enables the user to further assess semen parameters, including concentration, motility, pH, morphology, and vitality. The product is intended for adult male patients to assess sperm quality. The product is not intended to process any of the PHI/PII.

Seaman PRO for prescription use only.

Seaman PRO used with Imaging Hardware 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. Progressive motility (%)
4. pH value
5. Sperm morphology (normal forms, %)
6. Vitality (%)

The Seaman PRO device does not provide a comprehensive evaluation of a male's fertility status. Instead, it analyzes semen parameters which can be used by healthcare professionals as part of a broader assessment of 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.

SEAPRO Seaman PRO 510(k) Summary

Status:	Published
Version:	8.4
Date:	2026-04-09
Project:	QMS
Authors:	Paulina Burek (PABU)

Contents

510(k) Summary

This document provides a standardized template for preparing a 510(k) Summary in accordance with 21 CFR 807.92 and the guidance outlined in Appendices B and C of the FDA document 'The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]'.

1. Submitter

Company Name:	CheckCells, Inc.
Address:	6060 Center Dr, 10th floor, Los Angeles, CA 90045
Mail:	info@checkcells.com
Contact Person:	Martin Kosela
Date Prepared:	04/09/2026

2. Name of the Device

Proprietary Name:	Seaman PRO
Common or Usual Name:	Computer-Assisted Semen Analyzer
Classification Name:	Semen Analysis Device
Regulation Number:	21 CFR 864.5220
Product Code:	POV

3. Predicate Device

510(k) Number:	K180343
Predicate Device Name:	LensHooke X1 PRO Semen Quality Analyzer
Manufacturer:	Bonraybio Co., Ltd.

4. Device Description

The Seaman PRO device is an in vitro diagnostic system consisting of imaging hardware (a digital microscope with optics and USB camera) and software that uses AI-based algorithms to perform automated semen analysis. The system quantifies sperm concentration, total motility, progressive motility, morphology, vitality, and pH. The image processing and measurement logic is performed by software hosted on a PC workstation connected to the hardware. Data are output in a test report, with results calculated based on digital imaging of stained semen samples.

5. Intended Use of the Device

The Seaman PRO Analyzer is an automated, point-of-care, in vitro use-only medical device for semen analysis performed by healthcare professionals. The desktop unit consists of a light source, optical elements, and an image sensor connected to a PC, which records a video of the semen sample and sends it to the cloud compute unit. The cloud compute unit runs software containing algorithms for assessing semen parameters. The product is a software-based medical device powered by ML that enables the user to further assess semen parameters, including concentration, motility, pH, morphology, and vitality. The product is intended for adult male patients to assess sperm quality. The product is not intended to process any of the PHI/PII.

Seaman PRO for prescription use only.

Seaman PRO used with Imaging Hardware 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. Progressive motility (%)
4. pH value
5. Sperm morphology (normal forms, %)

6. Vitality (%)

The Seaman PRO device does not provide a comprehensive evaluation of a male's fertility status. Instead, it analyzes semen parameters that healthcare professionals use as part of a broader assessment of male fertility.

6. Technological Characteristics

The Seaman PRO system is an automated in vitro diagnostic device for human semen analysis. It consists of imaging hardware and software components designed for use in the point-of-care setting. The imaging hardware includes a desktop optical unit composed of a light source, fixed optical elements, and a digital image sensor. The unit captures video recordings of semen samples prepared on standard semen analysis microscope slides. The acquired image data is transferred to a connected PC and processed in a secure cloud compute environment. The software component is a Software as a Medical Device (SaMD) that uses image analysis algorithms, including machine learning (ML) techniques, to quantify semen parameters. These include: - Sperm concentration (10^6/mL) - Motility (total, progressive) - Vitality (%) - Sperm morphology (% normal forms) - pH value .The device provides direct and calculated quantitative outputs based on video analysis of sperm motility and morphology. The software does not interpret results or diagnose fertility status. It is intended to support healthcare professionals in assessing semen quality. The device does not process, store, or transmit any Protected Health Information (PHI) or Personally Identifiable Information (PII). The Seaman PRO device is intended for use in adult male individuals and are not to be used for post-vasectomy confirmation or in the diagnosis or treatment of disease. The device is intended for multiple uses and does not require patient-contact reprocessing. Only single-use sample carriers come into direct contact with the biological material. The reusable imaging hardware does not require sterilization and is cleaned using standard laboratory procedures.

7. Comparison to Predicate Device

7.1 Description

	Proposed Device	Predicate Device	Comparison
510(k) Number	K252228	K180343	N/A
Device Name	Seaman PRO	LensHooke X1 PRO Semen Quality Analyzer	N/A

Submitter	CheckCells Inc. 6060 Center Dr, 10th floor, Los Angeles, CA 90045	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	N/A
Product Code	21 CFR 864.5220	21 CFR 864.5220	Same

Indication for Use	The Seaman PRO Analyzer is an automated, point-of-care, in vitro use-only medical device for semen analysis performed by healthcare professionals. The desktop unit consists of a light source, optical elements, and an image sensor connected to a PC, which records a video of the semen sample and sends it to the cloud compute unit. The cloud compute unit runs software containing algorithms for assessing semen parameters. The product is a software-based medical device powered by ML that enables the user to further assess semen parameters, including concentration, motility, pH, morphology, and vitality. The product is intended for adult male patients to assess sperm quality. The product is not intended to process any of the PHI/PII. Seaman PRO for prescription use only. Seaman PRO used with Imaging Hardware is an optical device for human semen analysis, which	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 with a difference regarding the use of the cassette.

	provides direct and calculated quantitative measurements for: 1. Sperm concentration (10^6 per ml) 2. Total motility (PR+NP, %) 3. Progressive motility (%) 4. pH value 5. Sperm morphology (normal forms, %) 6. Vitality (%) The Seaman PRO device does not provide a comprehensive evaluation of a male's fertility status. Instead, it analyzes semen parameters that healthcare professionals use as part of a broader assessment of 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 (106 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.	

Platform	The Seaman PRO Analyzer is an automated point-of-care in vitro use-only medical device for semen analysis performed by healthcare professionals. The desktop unit consists of a light source, optical elements, and an image sensor connected to a PC that runs software containing algorithms for assessing semen parameters	The LensHooke X1 PRO Semen Quality Analyzer used with the LensHooke Semen Test Cassette is an optical device for human semen analysis.	Similar

Software Algorithm	Custom image analysis with AI	Custom image analysis with AI	Both rely on machine learning/image processing for sperm detection.
Hardware Configuration	Camera + optics + PC w/ AI software (modular)	Integrated desktop analyzer	Same principle of operation; modular setup does not impact functionality.

User Group	Seaman PRO: Healthcare Professional - Uses the system to create new tests, prepare samples, and retrieve the generated test reports for further analysis. Point-of-Care professional.	Point-of-Care professional / Over-the-Counter	Same

Patient population	• Male - all ages above 18, weights, and heights • No clinical knowledge but will be provided with instructions on how to use the product • A computer and internet literate person	Data nat available	Presumably Same

Sample Type	Human Semen	Human Semen	Same
Parameters	1. Vitality (%) 2. Sperm concentration (10^6 per ml) 3. Total motility (PR+NP, %) 4. Progressive motility (%) 5. Sperm morphology (normal forms, %) 6. pH value	1. Sperm concentration (10^6 per ml) 2. Total motility (PR+NP, %) 3. Progressive motility (%) 4. Non-Progressive motility (%) 5. Sperm morphology (normal forms, %) 6. pH value	Same with a difference of 1. and 8. Additional parameters are supplementary and do not impact core use.

Test Principle	Optical design and Image processing method Image analysis	Optical design and Image processing method Image analysis	Same
Test Type	Quantitative	Quantitative	Same
Control Materials	Hamilton Thorne Accu-beads+	X QC Beads, X QC Reticle	Equivalent
	Fertility Solutions Semen Test Recordings	LensHooke X QC Video (For Semen)	Equivalent

Reagents	Eosin Y, nigrosin	No	Not used in the Predicate Device Eosin Y is FDA-accepted; addition does not introduce new safety risks.
Accessories	Imaging hardware	Imaging hardware	Equivalent
Consumables	GoldCyto semen analysis slides	LensHooke Semen Test Cassette	Equivalent Both serve same function; physical design is different but compatible.

7.2 Comparison of Device Characteristics

Seaman PRO used with Imaging Hardware is an optical device for human semen analysis which provides direct and calculated quantitative measurements for (see below) with targets and dedicated limits:

No.	Parameter / Unit	Target Value	Range	Target Value	Range	Equivalence
Seaman PRO				**Lenshook X1 PRO Semen Quality Analyzer**		**N/A**
1.	Vitality (%)	>= 54%	0-100 %	N/A	N/A	Additional feature – does not change intended use
2.	Sperm concentration (M/ml)	>= 16 M/mL	Range: 0-380 M/mL Limit of Blank (LoB) = 0 M/mL Limit of Detection (LoD) = 1.9 M/mL Limit of Quantitation (LoQ) = 2.1 M/mL	16-200 M/mL	Range: 0-300 M/mL Limit of Blank (LoB) = 0 M/mL Limit of Detection (LoD) = 1.8 M/mL Limit of Quantitation (LoQ) = 7.2 M/mL	Equivalent. The subject device has a slightly extended upper measuring range (up to 380 M/mL compared to 300 M/mL); however, this difference does not raise new questions of safety or effectiveness and is supported by the linearity bench testing.
3.	Total motility (PR+NP, %)	>= 42%	<1 to 100 %	>= 42%	<1 to 100 %	Equivalent
4.	Progressive motility (%)	>= 30%	<1 to 100 %	>= 30%	<1 to 100 %	Equivalent

5.	Sperm morphology (normal forms, %)	>= 4%	<1 to 100 %	>= 4%	<1 to 100 %	Equivalent
6.	pH value	-	6.0 to 9.0	-	6.0 to 8.0	Equivalent

8. Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Verification and validation testing was conducted to demonstrate that the Seaman PRO Quality Analyzer device meets performance requirements and is substantially equivalent to the predicate device, LensHooke X1 PRO Semen Quality Analyzer (K180343).

8.1 Non-Clinical Tests Summary

Verification and validation testing was conducted to demonstrate that the Seaman PRO Semen Quality Analyzer devices meet performance requirements and are substantially equivalent to the predicate device, LensHooke X1 PRO Semen Quality Analyzer (K180343).

The conducted, comprehensive series, of nonclinical (bench) performance studies to support the analytical validity of the device. These studies were designed in accordance with applicable CLSI guidelines, WHO laboratory manual requirements, and ISO 23640:2015 standards, and include the following evaluations:

- **Repeatability (within-day precision)**:
  Conducted using two replicates per run, with two runs every four hours, five times per day, across multiple days. Testing involved three operator/analyzer/test cassette lot combinations for each sperm concentration, motility, and morphology level. Results confirmed that the coefficient of variation (CV%) for pH, sperm concentration, motility, and morphology remained within 10%, consistent with predicate performance.
- **Reproducibility (between-day and site-to-site precision)**:
  Assessed across three Point-of-Care sites over five days, using control solutions prepared at three levels (Low, Normal, High) for latex beads concentration and pH. Each sample was tested in five replicates by one operator per day. For motility and morphology—given sample degradation—reproducibility was assessed using three semen quality levels across the same time intervals as the repeatability test. Results showed consistent agreement across test sites and lots.
- **Linearity, LoB/LoD/LoQ**:
  Conducted using standard reference samples across the device's claimed measurement range. Data demonstrated linear response and defined analytical sensitivity parameters for all semen parameters. Limits of blank, detection, and quantification were determined following CLSI guidelines.

- **Interference Testing**:
  Common semen sample contaminants and interferences (vitamin B, testosterone, yeast, E. Coli, RBC, WBC, urine, saliva, agglutination, D-norgestrel, and β-estradiol) were tested to evaluate the robustness of measurements. No clinically significant interference was observed within the claimed range.
- **Sample Volume Studies**: Impact of sample volume on concentration, motility, morphology, vitality, and pH was assessed according to ISO 23640:2015. Acceptance criteria included CV ≤10% and bias ≤5%.
- **Environmental and Hardware Stability**:
  - Operating temperature and humidity stress tests confirmed functional stability under specified conditions.
  - Transport and accelerated aging studies confirmed that hardware maintains intended function and labeling legibility post-stress.

All tests met pre-defined acceptance criteria and demonstrate that the Seaman PRO device are safe, effective, and perform equivalently to the predicate device.

8.2 Clinical Tests Summary

To further evaluate the accuracy and effectiveness of the device in a clinical context, a measurement procedure comparison study was performed using human semen samples.

- **Subject Demographics: The clinical study evaluated N=300 human semen samples from adult males 18 years of age and older**.
- **Effectiveness Data:** Accuracy and analytical sensitivity were assessed by comparing the subject device's analysis against established reference procedures. **The study demonstrated strong agreement, yielding correlation coefficients exceeding 0.90 and regression slopes within the 0.90 to 1.10 range**.
- **Conclusion:** The clinical method comparison, alongside the non-clinical bench testing, confirms that the device meets its intended analytical performance claims and demonstrates that the subject device is substantially equivalent to the predicate device.

9. Conclusion

Seaman PRO device offers the measurement of the same parameters as the predicate device, and additionally offers the measurement of the sperm vitality as the percentage of the live sperm cells.

The Seaman PRO device is substantially equivalent to the predicate device LensHooke X1 PRO Semen Quality Analyzer (K180343) with respect to intended use, technological characteristics, and performance. Both devices are in-vitro diagnostic systems designed for quantitative analysis of human semen, targeting similar user populations in the POC setting.

The core measurement parameters—sperm concentration, motility (including total and progressive motility), morphology, and pH—are identical. The Seaman PRO device additionally includes vitality, which is supplementary and does not raise new questions of safety or effectiveness. The fundamental scientific technology, based on optical imaging and AI-assisted image analysis, remains the same.

Therefore, based on the provided comparison, performance equivalency, and technological justification, the Seaman PRO device is considered substantially equivalent to the predicate device LensHooke X1 PRO under 21 CFR 807.92.