August 21, 2025

NERv Technology Inc. D.B.A. FluidAI Medical
Mariam Al-Lami
QA/RA Manager
809 Wellington Street North
Unit 2
Kitchener, ON N2H 5L6
Canada

Re: K243965
Trade/Device Name: Origin™
Regulation Number: 21 CFR 862.1120
Regulation Name: Blood Gases (PCO2, PO2) And Blood pH Test System
Regulatory Class: Class II
Product Code: SFO
Dated: July 22, 2025
Received: July 22, 2025

Dear Mariam Al-Lami:

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,

Paula V. Caposino -S

Paula Caposino, Ph.D.
Deputy Director
Division of Chemistry and
Toxicology 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)*
K243965

Device Name
Origin™

Indications for Use *(Describe)*
The Origin™ system is comprised of the Origin™ inline device and Origin™ App. The Origin™ system is indicated for use in conjunction with a compatible drainage system by a trained healthcare professional during postoperative recovery in a hospital setting. The Origin™ inline device is placed between the surgical drainage catheter and reservoir system to continuously measure the pH of drainage fluid to provide additional information on effluent characteristics. The device is not intended to diagnose or treat any clinical condition.

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.

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"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."

510(k) Summary Document

1. **Submitter Information**:

Applicant

NERv Technology Inc. D.B.A FluidAI Medical
Unit 2, 809 Wellington St. N.,
Kitchener, ON, N2H 5L6, Canada

Applicant Contact

Mariam Al-Lami, QA/RA Manager
Phone: +1 (519) 722-3438
Email: mariam@fluidai.md

Date of Summary Preparation: Aug 21, 2025
510(k) Submission Number: K243965

2. **Device Information:**

Trade Name of the Device: Origin™
Common Name: Electrode Measurement, Blood-Gases (Pco2, Po2) And Blood pH
Product Code: SFO
Regulation Number: 862.1120

3. **Device Description:**

Origin™ is an inline biosensor system that is integrated between an off-the-shelf drainage catheter and reservoir system and is designed to monitor real-time changes in drained effluent characteristics. *Origin™ system* continuously monitors the pH of wound drainage. *Origin™ App* is a mobile application for displaying and analyzing data from the *Origin™ inline device. Origin™ App* is pre-installed on an Android mobile device supplied by FluidAI. The *Origin™* inline device connects to *Origin™ App* via Bluetooth.

4. **Indications for Use:**

The Origin™ system is comprised of the Origin™ inline device and Origin™ App. The Origin™ system is indicated for use in conjunction with a compatible drainage system by a trained healthcare professional during postoperative recovery in a hospital setting. The Origin™ inline device is placed between the surgical drainage catheter and reservoir system to continuously measure the pH of drainage fluid to provide additional information on effluent characteristics. The device is not intended to diagnose or treat any clinical condition.

5. Comparison of Technological Characteristics to Predicate

The following table summarizes the technological characteristics of the subject and predicate device. The devices have the same general intended use, and while there are differences in technological characteristics these differences do not raise new questions of safety and efficacy. Performance testing demonstrates equivalence between the subject and predicate device.

	Subject device	Predicate device
Device name	Origin™	ABL835 Flex Analyzer
Regulation number	862.1120	862.1120
Product classification	SFO	CHL
Intended Use	The measurement of pH in bodily fluids	Same
Indications for use	*The Origin™ system is comprised of the Origin™ inline device and Origin™ App. The Origin™ system is indicated for use in conjunction with a compatible drainage system by a trained healthcare professional during postoperative recovery in a hospital setting. The Origin™ inline device is placed between the surgical drainage catheter and reservoir system to continuously measure the pH of drainage fluid to provide additional information on effluent characteristics. The device is not intended to diagnose or treat any clinical condition.*	The pH measurement of pleural fluid can be a clinically useful tool in the management of patients with parapneumonic effusions.
pH measurement principle	Potentiometric measurement pH	Same
pH Electrode	Ion-sensitive field-effect transistor (ISFET)	glass ion-sensitive electrode (ISE)
Reference Electrode	Ag/AgCl	Same
Calibration method	1-point liquid calibration	2-point liquid calibration
QC solutions	Discrete syringes	Discrete bottles and ampoules
Measurement range	5-9 pH	7-7.5 pH
Sample type	Drain effluent	pleural fluid or blood
Sample application	continuous	discrete
Sample volume	N/A - continuous measurements	>=85uL
Sampling technique	Directly measures drain effluent continuously from patient	Point measurements of a patient sample of pleural fluid or whole blood
Resolution of display	0.01 pH	0.001 pH
Power Supply	Battery powered	Wall powered
Measurement Setting	Point of Care	Laboratory
Data Display	Mobile Device and Application	Built in the instrument
Measurement Temperature Range	18-40 °C	37 °C

6. Summary of Non-Clinical Testing:

1. Analytical Performance
   - **a. Precision**

The precision of Origin™ was evaluated with a study conducted at a single site using two continuous test setups circulating buffered and spiked donor human peritoneal drainage fluid at two pH levels (~6.3 and ~7.7), simulating 33% and 66% of the device's measuring range. In the precision study, the following were evaluated: within-run (repeatability), between-run, between-day, between-device, and within-laboratory precision (total). The study was done using 16 devices x 5 days x 3 runs x 12 replicates (n=2880). **Table 1** summarizes the precision study results for repeatability and within-lab precision.

Table 1: Origin™ precision study results.

Sample	N	Mean Value	Repeatability		Between-Run		Between-Day		Between-Device		Within-Laboratory	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
A	1440	6.303	0.0154	0.24%	0.0384	0.61%	0.0758	1.20%	0.0323	0.51%	0.0922	1.46%
B	1440	7.854	0.0190	0.24%	0.1426	1.82%	0.0809	1.03%	0.0000	0.00%	0.1650	2.10%

b. Linearity

The linear measuring range for Origin™ was evaluated using peritoneal drain fluid samples collected in the Method Comparison study (see section 6.1.d below). **Table** 1 summarizes the linearity study results.

Table 1: Origin™ linearity results.

pH range	Maximum Deviation from Linearity [pH units]
Overall (pH 5 to 9)	0.1446
pH 5 to 6	0.1446
pH 6 to 7	-0.0011
pH 7 to 8	-0.0102
pH 8 to 9	0.1129

An additional linearity study, using NIST traceable pH buffer solutions in the range of pH 4-10, was conducted. **Table** 3:2 Origin™ linearity results with pH buffer solutions. summarizes the linearity study results.

Table 3:2 Origin™ linearity results with pH buffer solutions.

Specification	Maximum Deviation from Linearity across pH 4 – 10 [pH units]
Linearity	0.1

c. *Interference*

Origin™ was tested against commonly encountered interferent substances. In this study, the effect of each interferent (at clinically relevant concentrations) on the pH measurements of Origin™ was measured through a paired difference test. This test occurred across two pH levels within the intended use range (pH 7 – Low and pH 8 – High) using simulated peritoneal fluids. The study produced one set of 16 paired observations per pH level (2 pH x n=16) for each interferent. No significant source of interference was determined from the testing of spiked simulated peritoneal fluids. The concentration of each of the tested interferent is listed in **Table 4.**

Table 4: Origin™ tested interference concentrations.

Interferent	Concentration (mg/dL, base mass)	Interferent Type
Bilirubin	60	Endogenous
Triglycerides	1667	Endogenous
Creatinine	75	Endogenous
Albumin (or total protein)	5300	Endogenous
Uric acid	31.2	Endogenous
Glucose	1000	Endogenous
Hemoglobin	1000	Endogenous
Morphine	0.78	Exogenous
Acetaminophen	7.8	Exogenous
Ibuprofen	36	Exogenous
Celecoxib	2.4	Exogenous
Ondansetron	0.0342	Exogenous
Cefoxitin	92.7	Exogenous
Metronidazole	12.3	Exogenous
Bupivacaine	1.05	Exogenous
Heparin	330 units/dL	Exogenous

d. **Comparison Studies**

Origin™ was compared against a glass pH probe in measuring 60 donor human peritoneal drain fluid samples. The study was conducted in 2 consecutive sets where each set was conducted over 6 days with 8 Origin™ devices compared to 4 glass pH probes. The measurements were done at the end of a 24-hour calibration period for Origin™ and represent the worst-case scenario bias. **Table 5** summarizes the method comparison results. **Figure 1**: Scatterplot of subject vs comparator pH measurements shows a scatterplot of the subject vs comparator pH measurements.

Table 5: Origin™ method comparison Results

pH range	Slope [95% CI]	Intercept [95% CI]	r^2	Mean bias [95% CI]
5-6	0.961 [0.770, 1.151]	-0.001 [-1.073, 1.071]	0.944	-0.223 [-0.263, -0.177]
6-7	0.936 [0.761, 1.112]	0.167 [-0.983, 1.318]	0.875	-0.251 [-0.298, -0.207]
7-8	1.369 [1.161, 1.578]	-2.899 [-4.482, -1.316]	0.839	-0.102 [-0.177, -0.022]
8-9	1.217 [0.914, 1.520]	-1.892 [-4.391, 0.606]	0.576	-0.105 [-0.155, -0.052]

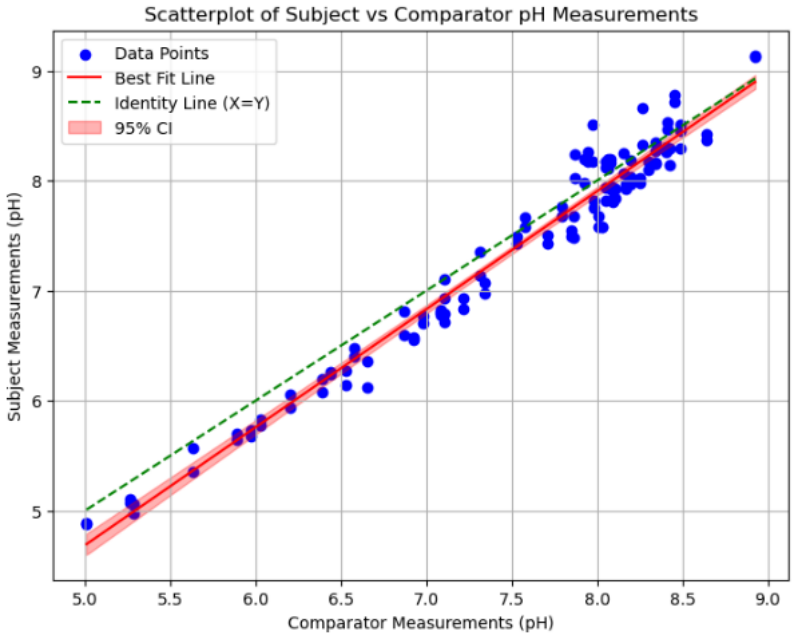

Figure 1: Scatterplot of subject vs comparator pH measurements

2. Functional Systems Testing

Functional systems testing was done to show that the device met all requirements.

3. Standards Compliance

The Origin™ system is designed and tested to be compliant with the following standards:

- IEC 62304:2006/AMD 1:2015 Medical device software – Software life cycle processes
- IEC 60601-1:2005 AMD1:2012 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014 AMD1:2020 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 61010-1:2010/AMD1:2016 – Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use
- IEC 61326-2-6 Edition 3.0 2020-10: Electrical equipment for measurement control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment

The following standard/guidance documents are referenced:

- CLSI EP05-A3 Evaluation of Precision of Quantitative Measurement Procedures, 3rd Edition
- CLSI EP06 Evaluation of Linearity of Quantitative Measurement Procedures, 2nd Edition
- CLSI EP07 Interference Testing in Clinical Chemistry, 3rd Edition
- CLSI EP09c Measurement Procedure Comparison and Bias Estimation Using Patient Samples, 3rd Edition
- CLSI EP37 Supplemental Tables for Interference Testing in Clinical Chemistry, 1st Edition
- CLSI EP39 A Hierarchical Approach to Selecting Surrogate Samples for the Evaluation of In Vitro Medical Laboratory Tests, 1st Edition

7. Conclusion

Based on the information presented in this submission it can be concluded that the subject device is substantially equivalent to the predicate device.