



**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT**

I Background Information:

A 510(k) Number

K243965

B Applicant

NERv Technology Inc. D.B.A. FluidAI Medical

C Proprietary and Established Names

Origin™

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
SFO	Class II	21 CFR 862.1120 - Blood Gases (PCO ₂ , PO ₂) And Blood pH Test System.	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

New device

B Measurand:

pH

C Type of Test:

Quantitative

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) 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.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

Origin™ has not been validated to aid in the diagnosis of disease conditions such as anastomotic leaks, ischemia, fistula, infection, sepsis, esophageal ruptures, congestive heart failure, tuberculosis, rheumatoid disease, pneumonia, and/or malignant disease. Do not use data provided by Origin™ to make a clinical decision or drive treatment or diagnosis. Doing so may cause serious harm to the patient.

The effects of Origin™ on downstream laboratory testing of drainage fluid have not been evaluated. It is recommended that sample fluid is collected prior to Origin™ attachment and/or prior to fluid passing through Origin™ for downstream laboratory testing.

D Special Instrument Requirements:

Origin™ (Inline Device) and Origin™ App

IV Device/System Characteristics:

A 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™ continuously monitors the pH of wound drainage. The Origin™ device comprises the following major components and accessories: Inlet Nozzle, Outlet Nozzle, Short Flexible Tubing, Long Flexible Tubing, Power Button, 3-way Stopcock, Status Light indicator, Reservoir Ring, Loop Ring, Tube Clamp, and safety pin. Internal components of Origin™ include electronic circuitry, batteries, and a flow cell with the pH sensor module.

Other equipment necessary for the proper use of Origin™ include:

- **Calibration syringes:** a set of three syringes per daily calibration, prefilled with calibrators used to calibrate and verify Origin™ sensors and ensure the accuracy of measurements.
- **Origin™ software application:** an application that is pre-installed on a compatible Android mobile tablet provided by *FluidAI Medical* And is used to interact with Origin™ and view patient data.

The claimed duration of device use is 5 days.

B Principle of Operation:

Origin™ measures the pH of drainage fluid by measuring the voltage difference (potentiometric) between a reference electrode (Ag/AgCl) and an Ion-Sensitive Field Effect Transistor (ISFET). An ISFET is made from a semiconducting material that is sensitive to hydrogen ions in a solution, and it measures the pH by directly measuring the activity of the H₃O⁺ ion, where “a” represents the hydrogen ion activity in the equation below.

$$pH = -\log a_{H_3O^+}$$

The ISFET changes its surface potential in proportion to the pH of the solutions it is exposed to. This change in surface potential is measured differentially against a stable reference potential, from the reference electrode, and can be converted to a pH reading by the following equation:

$$pH_{unknown\ solution} = \frac{E_{unknown\ solution} - E_{standard\ A}}{Sensitivity_{ISFET}}$$

Origin™ measures and automatically compensates for the actual temperature of the drainage fluid in its' flow cell in real-time. The Origin™ App calculates the temperature corrected pH and displays it by default using the following equation:

$$pH_{temperature\ corrected} = pH_{uncorrected} \times \frac{Fluid\ temperature_{at\ point\ of\ measurement}}{Fluid\ temperature_{at\ point\ of\ calibration}}$$

C Instrument Description Information:

1. Instrument Name:

Origin™

2. Specimen Identification:

Not applicable.

3. Specimen Sampling and Handling:

Not applicable.

4. Calibration:

Origin™ must be calibrated at the following times:

- After initial attachment of Origin™ inline device to the patient's drain system.
- Every 24 hours (at minimum) thereafter

Calibration should be performed with calibration syringes provided by the sponsor, which are pre-filled with NIST-traceable calibration fluids.

5. Quality Control:

Each calibration includes a syringe with verification fluid, which is used for verification of the Origin™ pH sensor.

V Substantial Equivalence Information:

A Predicate Device Name(s):

ABL835 FLEX analyzer

B Predicate 510(k) Number(s):

K110416

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K243965</u>	<u>K110416</u>
Device Trade Name	Origin™	ABL835 FLEX analyzer
General Device Characteristic Similarities		
Intended Use/Indications For Use	Measurement of pH	Same
Measurement Principle	Potentiometric measurement of pH	Same
Reference Electrode	Ag/AgCl	Same
General Device Characteristic Differences		
Measurement range	pH 5-9	pH 7-7.5
pH Electrode	Ion-sensitive field-effect transistor (ISFET)	Glass ion-sensitive electrode (ISE)
Sample type	Drain effluent	Pleural fluid or blood
Sample frequency	Continuous	Discrete
Calibration method	1 point liquid calibration	2-point liquid calibration

VI Standards/Guidance Documents Referenced:

- Clinical and Laboratory Standards Institute (CLSI) EP05-A3: Evaluation of Precision of Quantitative Measurement Procedures
- CLSI EP06: Evaluation of Linearity of Quantitative Measurement Procedures-2nd Edition
- CLSI EP07: Interference Testing in Clinical Chemistry - 3rd Edition
- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION: Medical device software — Software life cycle processes
- IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION: Basic Safety and Essential Performance of Electrical Medical Equipment and Electrical Medical Systems
- IEC 61010-1 Edition 3.1 2017-01 CONSOLIDATED VERSION: Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements
- IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION: Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests
- 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
- CLSI EP37 1st Edition: Supplemental Tables for Interference Testing in Clinical Chemistry
- CLSI EP39 1st Edition: A Hierarchical Approach to Selecting Surrogate Samples for the Evaluation of In Vitro Medical Laboratory Tests

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Repeatability Study

A study was conducted to evaluate the within-run (repeatability), between-run, between-day, between-device, and within-laboratory (total) precision of the Origin device when exposed to clinical peritoneal drainage fluid samples over its 5-day intended use period. The study was conducted using clinical peritoneal fluid at two pH levels (about 6.3 and 7.7). A total of 16 Origin devices were tested across two independent experimental sets by 4 operators. 3 runs were conducted per day (post-calibration, mid-day, pre-calibration the following day).

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%

Reproducibility Study

A study was conducted to evaluate the inter-device variability and reproducibility of Origin™. 10 Origin™ devices were included in this study, split between two, 5-device systems. Aqueous pH 6 and 8 buffers were fed through systems 1 and 2, respectively, using a gravity drip bag at various flow rates for five consecutive 24-hour periods. Measurements were taken continuously at a sampling rate of 25 seconds.

To demonstrate reproducibility and inter-device variability between devices, the collected data's CV (%) were calculated for every 25 second measurement available per system, per 24-hour period, across the 5 devices in each system.

Sample	Measurement	Day 1	Day 2	Day 3	Day 4	Day 5	Overall
System 1 (pH 6)	N	3434	3449	3456	3456	3453	17248
	Mean pH	5.9894	6.0548	6.0398	6.0449	6.0465	6.0351
	Average %CV	1.1792	0.5162	0.4509	0.4101	0.4126	0.5931
System 2 (pH 8)	N	3456	3457	3456	3454	3434	17257
	Mean pH	8.0712	8.0365	8.0343	8.0349	8.0372	8.0428
	Average %CV	1.9392	0.3013	0.2392	0.2967	0.3080	0.6173

2. Linearity:

A linearity study using NIST traceable pH buffer solutions in the range of pH 4-10 was conducted. The maximum deviation of linearity was 0.1 pH units.

Data from the Method Comparison study was also used to support the linearity of Origin™. A maximum deviation from linearity of 0.1446 pH units was observed.

3. Analytical Specificity/Interference:

An interference study was conducted to determine if Origin™ produces accurate and reliable results in the presence of 16 common endogenous and exogenous agents present in the intended patient population.

In the study, the effect of each interferent on the pH measurements of Origin™ was measured through a paired difference test. This test occurred across two pH levels (pH 7 – Low and pH 8 – High) using commercially available simulated peritoneal fluids. 16 paired observations were obtained per pH level for each interferent. No significant source of interference was determined from the testing of spiked simulated peritoneal fluids.

Interferent	Concentration (mg/dL, base mass)	Interferent Type
Bilirubin	60	Endogenous
Triglycerides	1667	Endogenous
Creatinine	75	Endogenous
Albumin (or total protein)	5300	Endogenous

Interferent	Concentration (mg/dL, base mass)	Interferent Type
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

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4. Assay Reportable Range:

The reportable range is pH 5-9.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

The Origin™ device is traceable to NIST standards.

6. Detection Limit:

The measuring range of the Origin device is pH 5 to 9.

7. Assay Cut-Off:

Not applicable.

8. Accuracy (Instrument):

See Method Comparison section VII.B.1. below.

9. Carry-Over:

Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

Origin™ was compared against a glass pH probe when measuring 60 donor human peritoneal drainage fluid samples. The study was conducted over 6 days with 8 Origin™ devices. The measurements used in the evaluation were taken at the end of a 24-hour calibration period for Origin™ to represent the worst-case scenario bias.

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]

2. Matrix Comparison:

Not applicable.

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Not applicable.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

Not applicable.

The labeling indicates that Origin™ has not been validated to aid in the diagnosis of disease conditions such as anastomotic leaks, ischemia, fistula, infection, sepsis, esophageal ruptures, congestive heart failure, tuberculosis, rheumatoid disease, pneumonia, and/or malignant disease. Do not use data provided by Origin™ to make a clinical decision or drive treatment or diagnosis. Doing so may cause serious harm to the patient.

F Other Supportive Instrument Performance Characteristics Data:

Not applicable.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.