510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K243543

B Applicant

iLine Microsystems S.L.

C Proprietary and Established Names

microINR System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
GJS	Class II	21 CFR 864.7750 Prothrombin Time Test	HE - Hematology

II Submission/Device Overview:

A Purpose for Submission:

Addition of new functionalities to the existing device

B Measurand:

International Normalized Ratio (INR)

C Type of Test:

Microfluidic technology with machine vision detection

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The microINR System measures prothrombin time (PT) expressed in International Normalized Ratio (INR), for monitoring oral anticoagulant therapy with warfarin.

The microINR System consists of a meter and chips (test strips) and uses fresh capillary whole blood from a fingerstick.

The microINR System is intended for patient self-testing use as well as for healthcare professionals at Point of Care settings.

The microINR System is intended for use in patients 18 years old or older. Patients must be stable on warfarin medication for at least 6 weeks before starting to use the microINR System.

For Self-testing use: The System is intended for properly trained users under specific prescription of a physician.

Caution: The microINR System is not intended for use in patients who are transitioning from heparin treatment to VKA therapy. The microINR System is not intended to be used for screening purposes.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

microINR Expert Meter

IV Device/System Characteristics:

A Device Description:

The microINR System is comprised of a portable measuring device (microINR Expert Meter) and test strips (microINR Chips) in which the capillary blood sample flows through capillary action. The microINR Chip contains a reagent in dried form which consists of thromboplastin, and contains two symmetrical regions, the measuring channel and a control channel. The microINR Expert Meter measures INR based on a prothrombin time (PT) assay carried out in the microINR Chip based on microfluidic technology with machine vision detection.

The microINR System has a multi-level on-board quality control. The microINR Control contains lyophilized human citrated plasma from healthy donors modified by means of a process to simulate an abnormal coagulation sample and a calcium chloride solution. The lyophilized plasma must be reconstituted with the calcium chloride solution before use.

The changes to the microINR Expert Meter include the incorporation of optional functions such as connectivity functions (Wi-Fi and Ethernet connectivity on top of the Bluetooth connectivity of the microINR Link), as well as other configurable settings (such as the option of including operator and patient identification), a touchscreen, a barcode scanner, a new QC (quality control)

mode. The modifications have no impact on fundamental scientific technology and its performance.

B Principle of Operation:

The microINR System is a handheld in vitro diagnostic medical device that uses microfluidic technology with machine vision detection to measure the prothrombin time from a fresh capillary (fingerstick) whole blood sample. The fresh capillary (fingerstick) whole blood sample is applied to the microINR Chip (test strip) for testing. The microINR Chip is inserted into the analyzer. Inside the test strip, the applied blood sample is separated into two channels and mixed with the reagents contained in each micro-reactor. The coagulation cascade is triggered instantly after mixing with the reagents (start time of the Prothrombin Time assay). When the blood coagulates its viscosity increases due to fibrin clot formation, which generates a sharp change in blood flow behavior. The Prothrombin Time measures how long it takes to form the fibrin clot after tissue thromboplastin has been added to the sample. The microINR Meter measures the International Normalized Ratio (INR) based on the Prothrombin Time (PT) assay carried out in the microINR Chip and displays the International Normalized Ratio (INR) on the screen.

V Substantial Equivalence Information:

A Predicate Device Name(s):
microINR Meter and microINR Link Meter

B Predicate 510(k) Number(s):
K180780 and K231711

C Comparison with Predicate(s):

Device & Predicate Device(s):	K243543	K231711	K180780
Device Trade Name	microINR System	microINR System	microINR System
General Device Characteristic Similarities			
Intended Use/Indications For Use	The microINR System measures prothrombin time (PT) expressed in International Normalized Ratio (INR), for monitoring oral anticoagulant therapy with warfarin. The microINR System consists of a meter and chips (test strips) and uses fresh capillary whole blood from a fingerstick. The microINR System is intended for patient self-testing	Same	The microINR System (consisting of the microINR Meter and the microINR Chip) is intended for multiple-patient use by professional healthcare providers for the determination of International Normalized Ratio (INR), to monitor Oral Anticoagulation Therapy (OAT) with

	use as well as for healthcare professionals at Point of Care settings. The microINR System is intended for use in patients 18 years old or older. Patients must be stable on warfarin medication for at least 6 weeks before starting to use the microINR System. For Self-testing use: The System is intended for properly trained users under specific prescription of a physician. Caution: The microINR System is not intended for use in patients who are transitioning from heparin treatment to VKA therapy. The microINR System is not intended to be used for screening purposes.		warfarin. The microINR system uses fresh capillary whole blood. The microINR System is intended for in vitro diagnostic use at the point-of-care. The microINR System is intended for use in patients 18 years of age and older. Patients must be stabilized (≥6 weeks) on warfarin. Caution: The microINR System is not intended for use in patients who are transitioning from heparin treatment to warfarin therapy. The microINR® System is not intended to be used for screening purposes.
Sample type	Capillary whole blood.	Same	Same
Operating Principle /Technology	Microfluidic technology with machine vision detection.	Same	Same
Test Strip Reagent	Human recombinant thromboplastin	Same	Same
Measuring Range	0.8 – 6.0 INR for professional use* 0.8 – 4.5 INR for self-testing use. (* INR visualization up to 4.5. Both uses commercialized under the same reference)	Same	0.8 – 6.0 INR for professional use NA for self-testing
Calibration traceability	Each lot of test strips is calibrated to a reference lot traceable to the WHO International Reference Preparation.	Same	Same
Reference Range	INR: 0.8 to 1.2	Same	Same
Calibration	Automatic, encoded on disposable, no end user input possible	Same	Same
Test Strip Stability	15 months	Same	Same
Test Strip Use Time	6 hours. (Limited to 15 minutes in IFU)	Same	6 hours

Sample Volume	A minimum of 3 µL	Same	Same
On-Board Quality Control	Multi-level on-board quality controls	Same	Same
Expiration data lock out	Automatic, encoded on disposable, no end user input possible	Same	Same
Limitations of POC settings	The microINR System is intended to be used in Point of Care settings such as physicians' offices and anticoagulation clinics, as well as home settings. It is not intended to be used in nursing homes, emergency rooms or intensive care units.	Same	No limitations
General Device Characteristic Differences			
External Liquid Quality Control	Yes (optional)	No	Yes
USB connectivity	Yes	No	Yes
Bluetooth connectivity	Yes (optional)	Yes	No
Patient ID	Yes (optional)	No	Yes (optional)
Memory Capacity	2,000 patient results and 500 quality control test results (results with time and date)	199 (results with time and date)	199 (results with time and date)
Display: Touchable screen	Yes	No	No
Barcode scanner	Yes	No	No
Wi-Fi connectivity	Yes (optional)	No	No
Ethernet connectivity	Yes (optional)	No	No
Ethernet adaptor	Yes (optional) (Sold separately)	No	No
Operator identification	Yes (optional)	Only time and date	Only time and date

VI Standards/Guidance Documents Referenced:

ISO 14971:2019 Medical devices - Application of risk management to medical devices.

IEC 62304:2006/AMD1:2015 Medical device software - Software life cycle processes.

IEC 60601-1-2:2014 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/COR1:2019 Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements.

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 60601-4-2:2024. Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

   Refer to K180780 and K201185.

2. Linearity:

   Refer to K180780.

3. Analytical Specificity/Interference:

   Refer to K180780.

4. Assay Reportable Range:

   Refer to K180780 and K201185.

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

   Refer to K180780.

6. Detection Limit:

   Refer to K180780.

7. Assay Cut-Off:

   Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   The method comparison study was performed at one external clinical site, using a total of 1384 patient capillary whole blood samples obtained during their regular anticoagulation follow up. The study was conducted using a total of 8 microINR Meters and 8 microINR Expert meters. Weighted Deming regression analysis was performed to assess the accuracy of the microINR Expert meters against the predicate device microINR Meters. All results met the pre-defined acceptance criteria.

N	Result Range	Correlation Coefficient (r)	Intercept (95% CI)	Slope (95% CI)
1384	0.9 – 6.9	0.987	0.001 (-0.028, 0.028)	1.001 (0.985, 1.015)

2. Matrix Comparison:

   Refer to K180780.

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):

   Usability study

   A usability study was conducted to demonstrate that the new functionalities of the microINR Expert System can be used safely and effectively by potential intended users after reading the labeling. Fifteen participants were enrolled in the study and performed the tasks after reading the labeling. All participants were able to successfully perform all the tasks (conduct a test, administrator identification, change meter settings and data consulting). The participants also participated in a questionnaire to survey the usability of the microINR System. On a scale of 1 to 5 where 1 is least favorable and 5 is most favorable, the mean score was 4.81, indicating that microINR Expert Meter system was easy to use.

   Additional testing on the modified device was conducted as follows: software verification and validation; testing for radiofrequency, electromagnetic compatibility and electrical safety; cybersecurity analysis and testing. All testing results met the pre-determined acceptance criteria. Based on the testing, the microINR System including the microINR

Expert Meter performs as intended, with no new questions of safety or effectiveness identified during testing.

The risk analysis of the implemented changes concluded that the microINR System including the microINR Expert Meter has no significant detectable risks compared to the predicate device and all residual risks have been deemed acceptable.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

Refer to K180780.

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.