July 21, 2025

iLine Microsystems S.L.
Miren Itsaso Hormaeche
Regulatory Affairs and Quality Director
Paseo Mikeletegi 69.
Donostia, 20006
Spain

Re: K251564
Trade/Device Name: microINR System
Regulation Number: 21 CFR 864.7750
Regulation Name: Prothrombin Time Test
Regulatory Class: Class II
Product Code: GJS
Dated: May 21, 2025
Received: May 22, 2025

Dear Miren Itsaso Hormaeche:

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,

Takeesha Taylor-bell -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)*
K251564

Device Name
microINR System

Indications for Use *(Describe)*
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 warfarin therapy. The microINR System is not intended to be used for screening purposes.

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.

510(k) SUMMARY

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

1. SUBMITTER INFORMATION

Owner	iLine Microsystems, S.L. Paseo Mikeletegi, 69 20009 Donostia, Guipúzcoa Spain
Contact	Miren Itsaso Hormaeche ihormaeche@ilinemicrosystems.com Tel. +34 943 005 651
Date Summary Prepared	July 08, 2025

2. DEVICE INFORMATION

Proprietary Name	microINR System (composed by the microINR Chips, microINR Kit, microINR Link Kit, microINR Expert Kit)
Common Name	Prothrombin time test
Panel	Hematology

Regulatory Information:

Classification				
Device	**Regulation Section**	**Device Class**	**Product Code**	**Test**
microINR System	21 CFR 864.7750	II	GJS	Prothrombin time test

3. SUBSTANTIAL EQUIVALENCE INFORMATION:

Element	Predicate Devices
Predicate Device Name	microINR System
Common Name	Prothrombin time test
510 (k) Number	K243543, K180780
Manufacturer	iLine Microsystems S.L.

4. DEVICE DESCRIPTION:

The microINR System design is maintained unchanged (as described in K243543). The fundamental scientific technology and test principle of the modified device has not changed from K243543 and K180780. Only SW changes are implemented to the INR visualization range in the microINR System meters. The change is for increasing the INR measuring range of the microINR System up to 8.0 and the removal of the limitation for LVAD patients.

The microINR System is comprised of a portable measuring device (microINR, microINR Link and 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 meters measure International Normalized Ratio (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. Multiple key functions and elements of the system are checked and if deviations are detected, error messages are displayed and test results are not reported.

5. INDICATIONS FOR USE/INTENDED USE:

The Intended Use and Indications for Use for the microINR System remain the same as the cleared microINR System (K201185, K231711, K243543):

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.

6. SUMMARY COMPARISON OF TECHNOLOGICAL CHARACTERISTICS (PREDICATE):

The microINR System is comprised of the microINR Chips and the microINR meters (microINR, microINR Link and microINR Expert meter). The fundamental scientific technology and test principle of the modified device has not changed from K243543 and K180780. Only SW changes are implemented to the INR visualization range in the microINR System meters. The change is for increasing the INR measuring range of the microINR System up to 8.0 and the removal of the limitation for LVAD patients.

7. STANDARD/GUIDANCE DOCUMENT REFERENCED:

No new standard/guidance documents used (previously submitted, reviewed and cleared under the premarket notifications for the microINR System K180780, K201185, K231711, K243543).

8. TEST PRINCIPLE

The microINR System has been cleared for self-testing and for professional use under different premarket notifications. The fundamental scientific technology and test principle of the modified device has not changed.

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 Chips (test strips) for testing. The microINR Chip is inserted into the analyzer. Two microcapillary channels in the test strip are filled with the blood sample by capillary action. The microINR Chip contains a preparation of human recombinant tissue factor, synthetic phospholipids and stabilizers. The microINR meters (microINR, microINR Link and microINR Expert meters) 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.

9. PERFORMANCE CHARACTERISTICS

The following characteristics have been previously submitted, reviewed and cleared under the premarket notification for the microINR System (K180780):

- Reproducibility/Intermediate Precision
- Linearity/Assay Reportable Range
- Traceability (Calibration)
- microINR® Chips Stability
- Detection Limit (Factor Sensitivity)
- Interfering Substances
- Clinical Method Comparison Study *
- Expected Values/Reference Range

These characteristics are not impacted by the changes implemented.

The use of the microINR System by self-testers was validated by an external user study that was conducted as the system is intended to be used. This study was submitted, reviewed and cleared under K201185.

* An additional method comparison study with untrained self-testers with high INR values has been performed to demonstrate the correct performance of the system up to INR 8.0 even when it is used by untrained patients.

The performance characteristics potentially affected by the new population tested (accuracy and precision) were evaluated:

Accuracy of the microINR System

1016 microINR System results with capillary blood from control subjects and patients recruited at ten clinical sites were compared to the results obtained in citrate venous plasma samples in a laboratory system ACL TOP 500 or ACL TOP 750:

microINR ystem vs Laboratory Reference device

N	Slope	Intercept	Pearson (r)
1016	1.00	0.08	0.97

Accuracy of the microINR System by self-testing patients

A Method Comparison Study was conducted at seven clinical sites comparing 461 INR test results obtained by self-testing patients to those obtained by healthcare professionals (HCP) using the microINR System:

microINR ystem (PSTs) vs Laboratory Reference device

N	Slope	Intercept	Pearson (r)
248	0.95	0.13	0.97

In addition, the 248 INR test results obtained by the self-testing patients were compared to the results obtained from citrate venous plasma samples in laboratory systems ACL TOP 500 or ACL TOP 750 as reference methods:

microINR ystem: PSTs vs HCPs

N	Slope	Intercept	Pearson (r)
461	0.99	0.02	0.98

Precision of the microINR System

Precision was determined based on duplicate measurements performed on 502 control subjects and patients at ten clinical sites:

	N test pairs	Mean	SD	CV %
INR < 2.0	131	1.46	0.07	4.9
2.0 ≤ INR < 4.5	337	2.79	0.14	5.0
INR ≥ 4.5	34	5.30	0.26	4.9

Precision of the microINR System by self-testing patients

The microINR System precision was determined based on duplicate measurements performed at four clinical sites by trained PSTs. The following results were obtained:

	Paired results
N	111
Mean	2.63
SD	0.13
CV (%)	4.9

The precision by untrained PSTs with high INR values was also determined based on duplicate measurements performed at three clinical sites:

	Paired results
N	13
Mean	5.64
SD	0.26
CV (%)	4.6

10. INSTRUMENT NAME

microINR meter, microINR Link meter and microINR Expert meter.

11. SYSTEM DESCRIPTION

The microINR System was previously cleared under premarket notification K180780, K201185, K231711 and K243543. The following characteristics remain the same:

11.1. Modes of Operation

The microINR System is a closed system, which is intended to be used exclusively with the microINR Chips manufactured by iLine Microsystems, S.L.

11.2. Software

The user interface of the microINR meters guides the user through the test procedure step by step. The user only needs to insert the Chip and apply a blood sample. The microINR System measures International Normalized Ratio (INR) based on a Prothrombin Time (PT) assay and displays the result. After the test is completed, the meter automatically saves the test result.

11.3. Specimen Sampling and Handling

The microINR Chip is intended for single-use only. Once the chip is inserted into the device, a drop of fresh capillary whole blood sample collected by fingerstick is manually applied to the Chip and analyzed by the microINR meter.

11.4. Calibration

Each lot of microINR Chips is calibrated to a reference lot of human recombinant thromboplastin traced to International Reference Thromboplastin of the World Health Organization.

These calibration parameters (International Sensitivity Index (ISI) and Mean Normal Prothrombin Time (MNPT)) are encoded in the printed Datamatrix of each microINR Chip along with information related to expiration date. Therefore, every test is automatically and individually calibrated eliminating any risk of human error.

11.5. Quality Control

The microINR System provides both meter´s functional Quality Controls and On-Board Quality Controls.

First, meter performance is automatically checked for electronic components, correct power battery level and environmental temperature conditions.

Then, On-Board Controls provide a quality control check for each individual microINR Chip used with the microINR meters. microINR System has been designed to detect errors prior to and during the test in order to prevent inaccurate INR results through a multi-level strategy.

12. CONCLUSION

The microINR System with the microINR Chips and the meters (microINR, microINR Link and microINR Expert meters) were previously cleared for self-testing use and professional use in CLIA waived settings under premarket notifications K201185, K231711 and K243543 for patients with INR up to 4.5 and with the exclusion of LVAD patients. The microINR System for professional use was cleared under K180780 for patients with INR up to 6.0 without any LVAD exclusion.

This premarket notification is being submitted to obtain clearance for the microINR System for self-testing use and professional use in CLIA waived settings with patients with INR up to 8.0 and for LVAD patients.

Based on the comparative analysis, the intended use, principles of operation, performance characteristics and technological characteristics, the microINR System has a good performance along the whole measuring range (up to 8.0) and no interference is observed with LVAD patients. The changed device does not introduce any new significant risks or any new questions of safety and effectiveness and as such, it is substantially equivalent to the predicate devices.