February 27, 2025

iLine Microsystems S.L.
Miren Itsaso Hormaeche
Regulatory Affairs and Quality Director
Paseo Mikeletegi, 69
Donostia, 20009
Spain

Re: K243543
Trade/Device Name: microINR System
Regulation Number: 21 CFR 864.7750
Regulation Name: Prothrombin time test
Regulatory Class: Class II
Product Code: GJS
Dated: December 5, 2024
Received: December 5, 2024

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,

Min Wu -S

Min Wu, Ph.D.
Branch Chief
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K243543

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 VKA 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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	February 26, 2025

2. DEVICE INFORMATION

Proprietary Name	microINR System (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	K180780, K201185, K231711
Manufacturer	iLine Microsystems S.L.

4. DEVICE DESCRIPTION:

The modified device microINR System containing the microINR Expert Meter is derived from the existing devices microINR Meter and microINR Link Meter. The change is for the incorporation of additional connectivity functions (Wi-Fi and Ethernet connectivity on top of the Bluetooth connectivity of the microINR Link), a touchscreen, a barcode scanner as well as other configurable settings and optional functions (such as the option of including operator and patient identification). All the actions related to the extra functionalities and configurable settings are set before or after performing the analytical test. The fundamental scientific technology of the modified device and its performance has not changed. No performance changes to the microINR System have been implemented since its initial clearance on K180780 and its home use clearance in K201185.

5. INDICATIONS FOR USE/INTENDED USE:

The addition of the new functionalities to the microINR meters is the focus of this 510(k) and does not alter the Intended Use or Indications for Use of the cleared system. The Intended Use and Indications for Use for the microINR System containing the microINR Expert Meter remain the same as the cleared microINR System (K201185 and K231711):

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 containing the microINR Expert Meter uses the same test strips (the microINR Chips) and measuring algorithm as the predicates, the microINR System for self-testing use and professional use in CLIA waived settings (K201185, K231711) and the microINR System only for professional use (K180780). The only changes are the addition of extra connectivity functionalities (Wi-Fi and Ethernet), a touchscreen display, a barcode scanner, and different configurable settings and optional functions (such as patient/operator identification). The performance characteristics of the microINR System remain the same.

7. TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

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; and Usability 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.

8. CONCLUSION

The microINR System with the microINR Meter and microINR Link Meter were previously cleared for self-testing use and professional use in CLIA waived settings under premarket notification K201185 and K231711.

This 510(k) is being submitted to obtain clearance for the microINR System including the microINR Expert Meter for patient self-testing, and CLIA waiver for professional use in Point of Care settings. The verification and/or validation activities required based on the Risk Analysis were evaluated and revealed that the extra functionalities were correctly implemented.

Based on the comparative analysis, the intended use, principles of operation, performance characteristics and technological characteristics, the microINR System including the microINR Expert Meter does not introduce any new significant risks or any new questions of safety and effectiveness. The difference in terms of extra functionalities between the subject and the predicate microINR System device raises no new issues of safety or effectiveness. Therefore, the microINR System containing the microINR Expert Meter is substantially equivalent to the predicate devices.