December 18, 2020

iLine Microsystems S.L.
c/o Marcia Zucker
Consultant
ZIVD LLC
62 Pollard Road
Plaistow, New Hampshire 03865

Re: K201185
Trade/Device Name: microINR System
Regulation Number: 21 CFR 864.7750
Regulation Name: Prothrombin Time Test
Regulatory Class: Class II
Product Code: GJS
Dated: April 27, 2020
Received: May 1, 2020

Dear Marcia Zucker:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

for Takeesha Taylor-Bell
Chief
Division of Immunology and Hematology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201185

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 microINR Meter and microINR Chip 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.

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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 Fax: +34 943 008 737
Date Summary Prepared	December 10, 2020

2. DEVICE INFORMATION

Proprietary Name	microINR® System
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 Device
Predicate Device Name	microINR® System
Common Name	Prothrombin time test
510 (k) Number	K180780
Manufacturer	iLine Microsystems

4. DEVICE DESCRIPTION:

The microINR® System is comprised of a portable measuring device (microINR® 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® Meter measures 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 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 microINR® Meter and microINR® Chip 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 following table compares the microINR® System with its predicate device, microINR® System for professional use (K180780).

Similarities		
Item	**microINR® System**	**microINR® System (K180780)**
Intended Use/Indications for Use (Differences highlighted in *italic*)	The microINR® System measures prothrombin time (PT) expressed in International Normalized Ratio (INR), for monitoring oral anticoagulant therapy with warfarin. *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.	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 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

Similarities		
Item	**microINR® System**	**microINR® System (K180780)**
	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.	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.
Operating Principle/Technology	Microfluidic technology with machine vision detection.	Same.
Operating Temperature	15 – 35ºC (59 – 95°F).	Same.
Test Strip Reagent	Human recombinant thromboplastin.	Same.
Measuring Range	0.8 – 4.5 INR.	0.8 – 6.0 INR.
Calibration traceability	Each lot of test strips is calibrated to a reference lot traceable to the WHO International Reference Preparation.	Same.
Reference Range	INR: 0.8 to 1.2.	Same.
Calibration	Automatic, encoded on disposable, no end user input possible.	Same.
Test Strip Stability	15 months.	Same.
Test Strip Use Time	6 hours. (Limited to 15 minutes in IFU).	6 hours.

Similarities		
Item	**microINR® System**	**microINR® System (K180780)**
Sample Volume	A minimum of 3 µL.	Same.
On-Board Quality Control	Multi-level on-board quality controls.	Same.
Memory Capacity	199 (results with time and date).	Same.
Hematocrit Range	Hematocrit ranges between 25-55% do not significantly affect test results.	Same.
Hemoglobin	No significant effect up to 1000 mg/dL.	Same.
Bilirubin	Bilirubin up to 40 mg/dL has no significant effect on test results.	Same.
Triglyceride	Lipemic samples containing up to 3270 mg/dL of triglycerides have no significant effect on test results.	Same.
Heparin	Use excluded in IFU.	Same.
Low Molecular Weight Heparin	Use excluded in IFU.	Same.
Expiration data lock out	Automatic, encoded on disposable, no end user input possible.	Same.

Differences		
Item	**microINR® System**	**microINR® System (K180780)**
Intended Use/Indications for Use	As indicated in the Similarities Table above.	
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.	No limitations.
External Liquid Quality Control	Not available.	External optional liquid quality controls.
EMC testing	IEC 60601-1-2:2014 (ESD testing 8kV contact and 15kV air discharges).	60601-1-2:2007 (ESD testing 6kV contact and 8kV air discharges).
SW	Date format: year with 4 digits. Error message E13 (control for chip US vs ROW models).	Date format: year with 2 digits. No E13 available.

Additional hardware and software changes have been made due to component obsolescence, to increase the resistance to electrostatic discharges or to resolve minor software anomalies (bugs). None of these modifications affects product performance.

7. STANDARD/GUIDANCE DOCUMENT REFERENCED:

In addition to the guidances previously submitted, reviewed and cleared under the premarket notification for the microINR® System (K180780), the following guidances have been followed:

- ANSI/AAMI ES60601-1 Medical electrical equipment – Part 1: General requirements for safety and essential performance,
- ANSI/AAMI IEC 60601-1-2 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests,
- IEC 60601-2-37 Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability,
- IEC 60601-1-11:2010 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment,
- IEC 62304 Medical Device Software - Software Life Cycle Processes,
- Format for Traditional and Abbreviated 510(k)s. Guidance for Industry and Food and Drug Administration Staff,
- Design Considerations for Devices Intended for Home Use, Guidance for Industry and Food and Drug Administration Staff,
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices. Guidance for Industry and Food and Drug Administration Staff.

8. TEST PRINCIPLE

The microINR® System was previously cleared for professional use under premarket notification K180780. The test principle has not been modified:
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® 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.

9. PERFORMANCE CHARACTERISTICS

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

- Precision/Repeatability
- 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 new user population.

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. Following training, the patients self-tested in the home setting for up to 2 weeks. The patients had 2 scheduled visits to their study site to collect patient vs. healthcare professional data in terms of accuracy and repeatability. The study results successfully demonstrated that trained patient self-testers can obtain results that are equivalent to those obtained by healthcare professionals. This study also demonstrated that self-testers are satisfied with the user-friendliness of the microINR® System.

The performance characteristics potentially affected by the new user population (accuracy and precision) were evaluated. The following information has been incorporated into the microINR® Chip instructions for use.

Accuracy

A Method Comparison Study was conducted at four clinical sites comparing the INR test results obtained by patient self-testers (PST) to those obtained by healthcare professionals (HCP) using the microINR® System in two visits to the sites (N = 225, Slope = 1.00, Intercept = 0.00 and Correlation Coefficient = 0.932).

The INR test results obtained at second visit by PST were compared to a laboratory system (ACL TOP 500) reference method (N = 112, Slope = 0.95, Intercept = 0.12, Correlation Coefficient r = 0.922).

The results indicate that microINR® System patient self-testers are able to obtain results as accurate as those obtained by healthcare professionals using the microINR® System.

Precision

The microINR® System precision was determined based on duplicate measurements performed at four clinical sites by patient self-testers in the second visit to the site. The following results were obtained:

	Paired results
N	110
Mean	2.61
SD	0.13
CV (%)	5.0

10. INSTRUMENT NAME

microINR® Meter.

11. SYSTEM DESCRIPTION

The microINR® System was previously cleared for professional use under premarket notification K180780. 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® Meter 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® Meter. 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 was previously cleared for professional use under premarket notification K180780.

This premarket notification is being submitted to obtain clearance for microINR System Home Use (i.e. patient self-testing), and therefore CLIA waiver for the professional use in Point Of Care settings. The performance characteristics that are affected by the new user population were evaluated and revealed that trained patient self-testers can obtain results on the microINR® System equivalent to those obtained by healthcare professionals.