August 14, 2026

Schiller AG
Jim Chickering
Regulatory Consultant
15 Belleau Woods
Georgetown, Massachusetts 01833

Re: K253562
Trade/Device Name: medilogFD
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: MWJ
Dated: July 21, 2026
Received: July 21, 2026

Dear Jim Chickering:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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); 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 Management System Regulation (QMSR) (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,

KIMBERLY N. CROWLEY -S

For: Jennifer Kozen
Assistant Director
DHT2A: Division of Cardiac Electrophysiology, Diagnostics, and Monitoring Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253562

Please provide the device trade name(s).

medilogFD

Please provide your Indications for Use below.

The medilogFD is an ambulatory ECG recorder intended to be used by or following instruction and under the direct supervision of a licensed physician in healthcare facilities or home environment to acquire, digitize, transmit and store data of up to a 12 lead ECG for a measuring duration of an extended period of 24 hours or more, including time point of the p-wave, R-peaks, time point of the pacemaker pulse, and ECG amplitudes.
The medilogFD is indicated for use in adults and children greater than 10 kg/22lbs who may be suspected to have cardiac rhythm disturbances or are otherwise directed for Holter monitoring such as in clinical research. The medilogFD is not protected against the effects of defibrillation. It is not indicated for life sustaining, life supporting or monitoring purposes nor for the treatment or alleviation of disease.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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1. Submitter's Name, Address, Contact Information

Manufacturer Information

Name	SCHILLER AG
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Consultant / Correspondent Information

Contact person	Jim Chickering
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Date the summary was prepared: August 10, 2026

2. Subject Device and Predicate Device

2.1. Subject Device

Device Name	medilogFD
Common or Usual Name	Holter Recorder
Classification Name	Electrocardiograph, Ambulatory (Without Analysis)
Device Class	II
Product code	MWJ
Regulation Number	21 CFR 870.2800

2.1. Predicate Device

Device Name	medilogAR4/medilogAR12
Device Manuf.	TOM MEDICAL ENTWICKLUNGS (Acquired by Schiller AG)
510(k) Number	K070818
Device Class	II
Product code	DSH
Regulation Number	21 CFR 870.2800

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2.1. Reference Device(s)

Device Name	NR Recorder
Device Manuf.	Norav Medical GmbH
510(k) Number	K161062
Device Class	II
Product code	MWJ
Regulation Number	21 CFR 870.2800

3. Device Description

The medilogFD subject device is a 9 channel, 12-lead Holter ECG recorder. It is intended for the long-term (typically 24 to 72 hours) ambulatory recording of electrical signals from the heart (ECG). The device is used with a 10-wire ECG patient cable and compatible electrodes. The device can be charged with a USB cable and power adapter, or a wireless charging station.

The subject device is indicated for use in adults and children greater than 10 kg (22lbs) who are suspected of having cardiac rhythm disturbances, or who are otherwise healthy and directed for Holter monitoring such as in clinical research. The preparation for the recording (attaching electrodes, etc.) is done by, or under the supervision of, a licensed physician and recording can be done in healthcare facilities or the home environment. During the ambulatory Holter recording, the device is worn and operated by an untrained patient.

The subject device stores and reports ECG waveform data at a Holter-quality frequency response, as specified in IEC 60601-2-47. It can also store and report ECG waveform data at a high-quality ECG frequency response. The medilogFD subject device stores the timepoint of ECG features that are detected in the recorded ECG waveform data, specifically: p-waves, R-waves and pacemaker pulses. It stores the measured amplitude of the QRS complex.

The medilogFD has the feature of recording 3-axis acceleration data, which allows the clinician to retrospectively review the patient's body activity level in a manner that is time-aligned with the ECG waveform data. The subject device also has the additional feature of storing pulse oximetry (SpO2) data that has been recorded by a 510(k)-cleared ambulatory pulse oximeter (Nonin 3150 WristOx2, cleared via K102350), which is also connected to the patient and pairs to the Holter via Bluetooth Low Energy (BLE).

At the end of the Holter measurement session, the recorded data is transferred via USB to a separate ECG analysis software program (not part of the subject device), where it

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can be viewed and analyzed by a trained clinician. ECG waveform data can also be transferred via Bluetooth during the measurement session either for a signal quality check, or for a compatible ECG analysis system to obtain approximately a 10 second snapshot of ECG data, for the purpose of use in a clinical research organization environment. The 10 second snapshot is for ECG *viewer* software. The medilogFD is not intended to be compatible with any marketed ECG analysis software; it must be evaluated for compatibility based on the ECG signal characteristics.

A summary of the medilogFD's ECG signal characteristics are as follows:

- Patient cable: 10 lead wires
- Electrode materials: wet hydrogel Ag-AgCl
- Number of recorded ECG channels: 9 channels
- Frequency response: 0.05 to 1000 Hz
- Input sample rate: 32 kHz to 128 kHz (depending on recording mode)
- Sample resolution: 12 bits
- ECG mains filtering: none
- ECG noise filtering: none
- Output and storage sample rate: 250 Hz (2000 Hz in Scientific mode)
- ECG Common Mode Rejection Ratio complies with IEC 60601-2-47: 2012
- ECG linearity and dynamic range complies with IEC 60601-2-47: 2012
- ECG input impedance complies with IEC 60601-2-47: 2012
- ECG gain accuracy complies with IEC 60601-2-47: 2012
- ECG timing accuracy complies with IEC 60601-2-47: 2012
- ECG system noise complies with IEC 60601-2-47: 2012

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4. Indications for Use

The medilogFD is an ambulatory ECG recorder intended to be used by or following instruction and under the direct supervision of a licensed physician in healthcare facilities or home environment to acquire, digitize, transmit and store data of up to a 12 lead ECG for a measuring duration of an extended period of 24 hours or more, including time point of the p-wave, R-peaks, time point of the pacemaker pulse, and ECG amplitudes.

The medilogFD is indicated for use in adults and children greater than 10 kg/22lbs who may be suspected to have cardiac rhythm disturbances or are otherwise directed for Holter monitoring such as in clinical research. The medilogFD is not protected against the effects of defibrillation. It is not indicated for life sustaining, life supporting or monitoring purposes nor for the treatment or alleviation of disease.

5. Comparison of Technological Characteristics

The subject device medilogFD has the same intended use as the predicate and reference devices. The differences in indications for use and technological characteristics between the subject device and predicate do not raise new or different questions of safety or effectiveness. The comparison of the subject device to the reference device for certain features and technology characteristics show the methods to evaluate these features are acceptable and the results of the characterization or verification are equivalent to the reference.

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Characteristic	Subject Device medilogFD Holter ECG Recorder	Primary Predicate Device - medilogAR4/AR12	Reference Device K161062 – NR Recorder	Discussion
K #	**K253562**	**K070818**	**K161062**	**--**
Classification	21 CFR 870.2800	21 CFR 870.2800	21 CFR 870.2800	Identical
Product code	MWJ	DSH	MWJ	Comparable as subject, predicate, and reference devices are medical magnetic recorders and ambulatory ECG recorders
Indications For Use Statement	The medilogFD is an ambulatory ECG recorder intended to be used by or following instruction and under the direct supervision of a licensed physician in healthcare facilities or home environment to acquire, digitize, transmit and store data of up to a 12 lead ECG for a measuring duration of an extended period of 24 hours or more, including time point of the p-wave, R-peaks, time point of the pacemaker pulse, and ECG amplitudes. The medilogFD is indicated for use in adults and children greater than 10 kg/22lbs who	The medilogAR4, medilogAR12 Digital Holter Recorder is used to record a 3 channel ECG and to measure the time intervals between consecutive R peaks in the ECG. The system is designed for a measuring duration of more than 24h and is therefore worn by the patient throughout the whole day. The preparation for the recording (attaching electrodes, etc.) is undertaken by the technician or doctor. During the recording, the instrument is carried in a special protective pouch which can be attached to a belt. The instrument is not designed for emergency monitoring purposes (intensive medical monitor); the instrument is only designed to	The NR recorder is intended for patients requiring: • Ambulatory (Holter) monitoring • Use within the physician office setting by the medical professional • Resting ECG monitoring (using Bluetooth communication) • Telemetry ECG monitoring (using Bluetooth communication) Such monitoring is most frequently used for the indications below:	Differences do not create new intended use, or raise different questions of safety or effectiveness. The subject, predicate and reference devices are intended for ambulatory recording of ECGs in home healthcare and professional environments. They are not intended for real-time monitoring.

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Characteristic	Subject Device medilogFD Holter ECG Recorder	Primary Predicate Device - medilogAR4/AR12	Reference Device K161062 – NR Recorder	Discussion
K #	**K253562**	**K070818**	**K161062**	**--**
	may be suspected to have cardiac rhythm disturbances or are otherwise directed for Holter monitoring such as in clinical research. The medilogFD is not protected against the effects of defibrillation. It is not indicated for life sustaining, life supporting or monitoring purposes nor for the treatment or alleviation of disease.	record the ECG and/or information derived from ECG. The recorder is not protected against the effects of defibrillation as outlined in EN60601-2-25. The instrument also records other information: HF component of the ECG, time point of the p-wave, time point of the T-wave, and time point of the pacemaker pulse, and ECG amplitude. Such monitoring is most frequently used for the indications below: - Evaluation of symptoms suggesting arrhythmia or myocardial ischemia. - Evaluation of ECG documenting therapeutic interventions in individual patients or groups of patients. - Evaluation of patients for ST segment changes (no online ST measurement implemented in recorder) - Evaluation of a patient's response after resuming occupational or recreational activities (e.g., after M.I. or cardiac surgery) - Clinical and epidemiological research studies. - Evaluation of patients with pacemakers	• Evaluation of symptoms suggesting arrhythmia or myocardial ischemia • Evaluation of ECG documenting therapeutic interventions in individual patients or groups of patients • Evaluation of patients for ST segment changes • Evaluation of a patient's response after resuming occupational or recreational activities (for example, after myocardial infarction or cardiac surgery) • Clinical and epidemiological research studies • Evaluation of patients with pacemakers • Reporting of time and frequency domain heart rate variability • Reporting of QT interval	

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Characteristic	Subject Device medilogFD Holter ECG Recorder	Primary Predicate Device - medilogAR4/AR12	Reference Device K161062 – NR Recorder	Discussion
K #	**K253562**	**K070818**	**K161062**	**--**
		- Reporting of time and frequency domain heart rate variability (no online calculation implemented in recorder) - Reporting of QT interval (no online QT interval measurement implemented in recorder)		
Rx / OTC Status	Prescription device	Prescription device	Prescription device	Identical
Patient Population	Adults and Children	Adults and Children	Adults and Children	Subject, reference, and reference devices can be used with adults and children.
Display	Color OLED display	Status LEDs	High resolution color graphic display	Comparable – differences do not affect safety or effectiveness
Device Energy Type	Single use alkaline and rechargeable battery power (via USB or wireless)	Alkaline battery powered (not rechargeable)	Alkaline battery powered, or rechargable lithium battery powered	Comparable – differences do not affect safety or effectiveness
User Input Mechanisms	Navigation buttons (event), microphone (physician recording), device tapping	Event button	Navigation buttons, event buttons Microphone	Comparable – differences do not affect safety or effectiveness
Connectivity Mechanisms	USB, Bluetooth	Removable compact flash, infrared (IR) wireless link	USB, Bluetooth, SD Card	Comparable wireless connectivity. Reference and subject devices both use Bluetooth protocols

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Characteristic	Subject Device medilogFD Holter ECG Recorder	Primary Predicate Device - medilogAR4/AR12	Reference Device K161062 – NR Recorder	Discussion
K #	**K253562**	**K070818**	**K161062**	**--**
Holter Configuration	USB, Bluetooth, or physician voice recording (patient ID)	Via IR link	USB, Bluetooth, or physician voice recording (patient ID)	Comparable wireless connectivity. Reference and subject devices both use Bluetooth protocols and voice recording.
Holter Data Transfer and Compatibility	USB Live signal viewing via Bluetooth Transfer to separate compatible Holter ECG Analysis System(s)	Via IR link or memory card Transfer to separate ECG Analysis System	USB Live signal viewing via Bluetooth Transfer to separate ECG Analysis System(s)	Comparable transfer connectivity. Reference and subject devices both use Bluetooth protocols and include real-time signal viewing. Data analysis is performed by a separate ECG system using proprietary data protocols.
Recording of Movements	Yes, integrated accelerometer	No	Yes, integrated accelerometer	Accelerometer is same between subject and reference devices and does not raise different questions of safety or effectiveness.
Recording of SpO2	Yes, compatible with Nonin 3150 WristOX (K102350)	No	No	The subject device pairs with the Nonin WristOX via Bluetooth and transfers its recordings to the subject device's memory card. The subject device does not display, modify or analyze the SpO_2 data so it does not raise different questions of safety or effectiveness
Ambulatory ECG system performance	Compliance with 60601-2-47	Compliance with 60601-2-47	Compliance with 60601-2-47	Equivalent

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Characteristic	Subject Device medilogFD Holter ECG Recorder	Primary Predicate Device - medilogAR4/AR12	Reference Device K161062 – NR Recorder	Discussion
K #	**K253562**	**K070818**	**K161062**	**--**
Patient Cable	10 lead wires	3, 5 or 7 lead wires	3, 4, 5, 7 or 10 lead wires	Cables are comparable between subject and reference devices; differences between subject and predicate do not raise different questions of safety or effectiveness.
Recorded Channels	9-channels	3-channels	3, 6 or 12	Channels are comparable between subject and reference devices; differences between subject and predicate do not raise different questions of safety or effectiveness.
Sampling and Storage Characteristics	Compliance with 60601-2-47 and the signal quality clauses of 60601-2-25	Compliance with 60601-2-47	Compliance with 60601-2-47 and 60601-2-25	Subject, predicate, and reference devices meet the same ambulatory recording standards. Subject and reference meet signal quality requirements of 60601-2-25.
Reported ECG Annotations	Timepoint of detected pacemaker pulse Timepoint of detected p-wave Timepoint of detected R-wave Amplitude of QRS complex	Timepoint of detected pacemaker pulse Timepoint of detected p-wave Timepoint of detected R-wave Timepoint of detected T-wave Amplitude of QRS complex	Timepoint of pacemaker pulse	Equivalent ECG annotations between predicate and subject devices.

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6. Non-Clinical Performance Data

6.1. Electrical Safety

Rec.#	Standard Year (ed.)	Title
19-46	ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]	Medical electrical equipment—Part 1: General requirements for basic safety and essential performance

6.2. EMC

Rec.#	Standard Year (ed.)	Title
19-36	ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021]	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

6.3. Other Non-Clinical Performance Testing

Rec.#	Standard Year (ed.)	Title
5-132	IEC 60601-1-6 Edition 3.2	Medical electrical equipment Part 1-6 General requirements for safety - Collateral Standard: Usability
5-129	ANSI AAMI IEC 62366-1:2015+AMD1:2020	Medical devices Part 1: Application of usability engineering to medical devices, including Amendment 1
3-155	ANSI AAMI IEC 60601-2-47:2012/(R)2016	Medical electrical equipment -- Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
19-47	ANSI AAMI HA60601-1-11:2015	Medical Electrical Equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral Standard: Requirements for medical electrical equipment and medical electrical equipment and medical electrical systems used in the home healthcare environment (IEC 60601-1-11:2015 MOD) [Including Amendment1 (2021)]
2-258	ANSI AAMI ISO10993-1: 2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
19-33	IEC 62133-2 Edition1.0 2017-02	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

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Rec.#	Standard Year (ed.)	Title
3-129	ANSI/AAMI EC53:2013/(R)2020	ECG trunk cables and patient leadwires
5-135	ISO 20417 First edition 2021-04 Corrected version 2021-12	Medical devices - Application of risk management to medical devices

Nonclinical bench testing, including a 20-subject usability validation, standards-based evaluations as well device-specific functional and performance testing was conducted on the medilogFD to demonstrate that the device met all of its requirements, and was equivalent to the predicate device and applicable reference device characteristics.

6.4. Software Verification and Validation Testing

Rec.#	Standard Year (ed.)	Title
13-79	ANSI AAMI IEC 62304:2006/A1:2016	Medical device software Software life-cycle processes [including Amendment 1 (2016)]
13-83	AAMI TIR57:2016	Principles for medical device security - Risk management.

The subject device has been designed and developed in accordance with recognized standards, internal software development processes, and FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, and FDA Content of Premarket Submissions for Management of Cybersecurity in Medical Devices.
Software verification and validation testing was performed at the unit, integration and system levels. Cybersecurity threat modeling and penetration testing was performed.

7. Clinical Testing

No clinical testing was performed to support this premarket notification.

8. Conclusion

The nonclinical verification and validation testing, along with compliance to recognized standards, demonstrates the medilogFD is substantially equivalent to the predicate device (K070818), and is as safe and effective as both the predicate and reference device (K161062).