November 10, 2025

Withings
Aline Criton
Chief Clinical and Regulatory Affairs Officer
2 Rue Maurice Hartmann
Issy-les-Moulineaux, IDF 92130
France

Re: K252474
Trade/Device Name: Withings BeamO (SCT02)
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS, SDV, DQD
Dated: August 6, 2025
Received: October 8, 2025

Dear Aline Criton:

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); 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,

JENNIFER W. SHIH -S

Jennifer Kozen
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
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.	K252474

Please provide the device trade name(s).

Withings BeamO (SCT02)

Please provide your Indications for Use below.

Withings BeamO is intended to record, display (when prescribed or used under the care of a physician), store, and transfer single-channel electrocardiogram (ECG) rhythms. It is indicated for use with individuals 22 years and older.

Withings BeamO is a non-sterile, contactless, reusable clinical thermometer intended for the intermittent determination of human body temperature over the temporal artery as the measurement site on people of all ages.

Withings BeamO is also an electronic stethoscope that enables the recording and transmission of auscultation sound data. Withings BeamO is intended to be used by professional users in a clinical environment or by lay users in a non-clinical environment on people of all ages. The electronic stethoscope is for medical diagnostics purposes only. The device is not intended for self-diagnosis.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D)

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

510(k) Summary

1. Submitter

510(k) Number	K252474
Applicant:	Withings 2 Rue Maurice Hartmann Issy-Les-Moulineaux France 92130
Submission Correspondent:	Aline Criton Chief Clinical and Regulatory Affairs Officer Phone: +33 6 64 20 47 65 Email: aline.criton@withings.com
Date Prepared:	November 10, 2025

2. Subject Device Information

Device Name:	Withings BeamO
Model Name:	SCT02
Regulation Name:	Electrocardiograph, Clinical Electronic Thermometer, Electronic Stethoscope Transmitters and Receivers, Telephone
Regulation Number:	21 CFR 870.2340 21 CFR 870.1875 21 CFR 880.2910
Regulatory Class:	Class II
Product Code:	DPS
Subsequent Product Code	SDV, DQD
510(k) review panel:	General Hospital, Cardiovascular

3. Predicate Device Information

Primary predicate manufacturer:	AliveCor
Primary predicate device name:	AliveCor Heart Monitor OTC
Primary predicate 510(k) Number:	K130921
Secondary predicate manufacturer:	Withings
Secondary predicate name:	Withings Thermo
Secondary predicate 510(k) Number:	K160544

Secondary predicate manufacturer:	Tyto
Secondary predicate name:	Tyto Stethoscope
Secondary predicate 510(k) Number:	K181612
Reference device manufacturer:	Eko Model E5 System (EME5)
Reference device name:	Eko Devices
Reference device 510(k) Number:	K170874

4. Description of the Device

Withings BeamO, model name SCT02, is a multi-function handheld battery powered device with ECG, stethoscope, temperature capabilities. Withings BeamO can record a 1-lead ECG using two stainless steel electrodes. It analyzes the data collected by the integrated two stainless steel electrodes to generate an one-lead ECG waveform and provides the ECG recording to the user for a given 30 second measurement.

Withings BeamO is also a contactless thermometer that can measure body temperature in adjusted mode.

Withings BeamO is also a digital stethoscope that can be used to auscultate heart and lung sounds. The sensor generates an electric charge when subjected to mechanical vibrations. The charge variations are amplified and digitized by an audio codec. Sound filters are applied to the resulting sound wave in order to listen to the patient's heart and lung sounds with clarity.

Withings BeamO consists of hardware and embedded software. Withings BeamO works in conjunction with a companion software on the Withings App. Withings BeamO communicates with the companion software via Bluetooth Low Energy (BLE). The device measurement results and recordings are synchronized with the companion software using Wi-Fi/Cellular data via the Withings servers.

Withings BeamO does not include ECG analysis or ECG-derived heart rate functionalities.

5. Intended Use/Indications for Use

Withings BeamO is intended to record, display (when prescribed or used under the care of a physician), store, and transfer single-channel electrocardiogram (ECG) rhythms. It is indicated for use with individuals 22 years and older.

Withings BeamO is a non-sterile, contactless, reusable clinical thermometer intended for the intermittent determination of human body temperature over the temporal artery as the measurement site on people of all ages.

Withings BeamO is also an electronic stethoscope that enables the recording and transmission of auscultation sound data. Withings BeamO is intended to be used by professional users in a clinical environment or by lay users in a non-clinical environment on people of all ages. The electronic stethoscope is for medical diagnostics purposes only. The device is not intended for self-diagnosis.

6. Comparison to the Predicate and Reference Devices

Description	Subject Device Name: Withings BeamO, Subject device model name: SCT02	Primary Predicate: AliveCor Heart Monitor OTC	Secondary Predicate Device: Withings Thermo	Secondary Predicate: Tyto Stethoscope	Reference device: Eko Model E5 System (EME5), Eko DUO	Comparison to Predicate Devices
Device Name	Withings BeamO	AliveCor Heart Monitor OTC	Withings Thermo	Tyto Stethoscope	Eko Model E5 System (EME5), Eko DUO	N/A
Manufacturer	Withings	AliveCor	Withings	Tyto Care Ltd.	Eko Devices, Inc.	N/A
510(k)	K252474	K130921	K160544	K181612	K170874	N/A
Regulation Number	21 CFR 880.2910 21 CFR 870.1875 21 CFR 870.2340	21 CFR 870.2340	21 CFR 880.2910	21 CFR 870.1875	21 CFR 870.1875	Similar to predicates and reference devices
Class	Class II	Class II	Class II	Class II	Class II	Same
510(k) Review Panel	General Hospital Cardiovascular	Cardiovascular	General Hospital	Cardiovascular	Cardiovascular	Similar to predicates
Device Class/Name	Electrocardiograph Clinical Electronic Thermometer Electronic Stethoscope	Electrocardiograph	Clinical Electronic Thermometer	Electronic Stethoscope	Electronic Stethoscope	Similar to predicate and reference devices
Product Code	DPS, DQD, SDV	DPS	FLL	DQD	DQD	Similar to predicate and reference devices. The SCT02 temperature function is considered under product code SDV (exempt clinical electronic thermometer), whereas the predicate Withings BeamO was cleared before the exemption under product code FLL (continuous measurement thermometer).
Intended Use/ Indications for Use	Withings BeamO is intended to record, display (when prescribed or used under the care of a	The AliveCor Heart Monitor is intended to record, display (when prescribed or used under the care	The Withings Thermo (Model SCT01) is a non-sterile, contactless, reusable clinical	The Tyto Stethoscope is an electronic stethoscope that enables	The Eko Model E5 System is intended to be used by healthcare professionals to	Same. Both the subject device and the primary predicate devices record a one-lead

	physician), store, and transfer single-channel electrocardiogram (ECG) rhythms. It is indicated for use with individuals 22 years and older. Withings BeamO is a non-sterile, contactless, reusable clinical thermometer intended for the intermittent determination of human body temperature over the temporal artery as the measurement site on people of all ages. Withings BeamO is also an electronic stethoscope that enables the recording and transmission of auscultation sound data. Withings BeamO is intended to be used by professional users in a clinical environment or by lay users in a non-clinical environment on people of all ages. The electronic stethoscope is for medical diagnostics purposes only. The device is not intended for self-	of a physician), store and transfer single-channel electrocardiogram (ECG) rhythms.	thermometer intended for the intermittent determination of human body temperature over the temporal artery as the measurement site on people of all ages.	transmission of auscultation sound data, whereby a clinician at one location on an IP network can listen to the auscultation sounds of a patient on site or at a different location on the IP network with the signal carried on an IP connection between the two locations. The Tyto Stethoscope is intended to be used by professional users in a clinical environment or by lay users in a nonclinical environment. The device is for medical diagnostics purposes only. The device is not intended for self-diagnosis.	electronically amplify, filter, and transfer body sounds and single-channel electrocardiogram (ECG) waveforms. The Eko Model E5 System also displays ECG waveforms and phonocardiogram waveforms on the accompanying mobile application for storage and sharing (when prescribed or used under the care of a physician). It can be used to record heart sounds and cardiac murmurs, bruits, respiratory sounds, and abdominal sounds during physical examination in normal patients or those with suspected diseases of the cardiac, vascular, pulmonary, or abdominal organ systems. The device can be used on adults and pediatrics. The data offered by the device is only significant when used in conjunction with physician over read as well as	ECG using two stainless steel electrodes, the same as the secondary predicate device. For both devices, the first ECG activation must be performed under the care of a physician. The subject device has two additional functions (stethoscope, and temperature) that the primary predicate does not have. The intended use of the subject device for stethoscope and temperature functionalities is the same as the secondary predicate and reference devices.

	diagnosis.				consideration of other relevant patient data. The device should not be used on infants weighing less than 10kg.	
Medical Functions	- One-lead ECG recording - Temperature measurement - Stethoscope for recording heart and lung sounds	One-lead ECG recording	Temperature measurement	Stethoscope for recording heart and lung sounds	- Stethoscope for recording heart and cardiac murmurs, bruits, respiratory sounds, and abdominal sounds during physical examination in normal patients or those with suspected diseases of the cardiac, vascular, pulmonary, or abdominal organ systems -One-lead ECG	Similar to predicates and reference devices
Intended population	Intended to be used on people of all ages for the temperature function. Intended to be used on people of all ages for the stethoscope function. Intended to be used on individuals 22 years and older for the ECG function.	Intended to be used on adults for the ECG function.	Intended to be used on people of all ages for the temperature function.	Intended to be used on adults for the stethoscope function.	Intended to be used on adults and pediatrics for the stethoscope function.	Similar to predicates and reference devices
Intended Operator	This medical device is intended to be used or operated by adults only	Adults	Adults	Adults	Adults	Similar to predicates and reference devices

	(referred to as active patients).					
Environment of Use	Home and Professional healthcare facilities	Home and Professional healthcare facilities	Home	Home and Professional healthcare facilities	Professional healthcare facilities	Similar to predicates and reference devices
Prescription/OTC	OTC and Prescription	OTC and Prescription	OTC	OTC	Prescription	Similar to predicates and reference devices

Table 1: High-level Comparison for intended use between the subject device, and predicate and reference devices

The subject device is intended to record, display (when prescribed or used under the care of a physician), store and transfer single-channel electrocardiogram (ECG) rhythms same as the primary predicate device AliveCor Heart Monitor. Both devices are indicated for use with individuals 22 years and older.

The subject device and the secondary predicate device have the same intended use for the temperature feature. Both devices are intended for a no contact intermittent determination of human body temperature over the forehead temporal artery.

The subject device is also an electronic stethoscope intended for recording and transmission of auscultation sound data same as the secondary predicate device Tyto Care Stethoscope and reference device Eko Model E5.

Therefore, the intended use of the subject device, the primary predicate device, the secondary predicate and reference devices in relation to temperature, stethoscope, and ECG function is the same.

7. Summary of Performance Testing

Non-Clinical Testing

All necessary performance testing was conducted on the subject device to support a determination of substantial equivalence to the primary predicate device, secondary predicates and reference devices. This testing included testing to the following FDA recognized standards and FDA guidance documents:

- ANSI/AAMI ES60601-1:2005/(R) 2012 and A1:2012, C1:2009/(R) 2012 and A2:2010/(R)2012 Medical Electrical Equipment – Part 1: General Requirements For Basic Safety And Essential Performance,
- IEC 60601-1-2:2014 Medical Electrical Equipment – Part 1-2: General Requirements For Basic Safety And Essential Performance – Collateral Standard: Electromagnetic Compatibility Requirements And Tests, and
- IEC 60601-1-11: 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 60601-2-47: Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
- ISO 10993-5 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10: Biological evaluation of medical devices Part 10: Tests for skin sensitization
- FDA guidance document, “Applying Human Factors and Usability Engineering to Medical Devices”
- FDA guidance document, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"
- FDA guidance “Content of Premarket Submissions for Device Software Functions, June 14, 2023”
- [510(K)] Submissions for Clinical Electronic Thermometers MARCH 1993
- ISO 80601-2-56 Second edition 2017-03: Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. [Including: Amendment 1 (2018)].
- AAMI TIR69:2017/(R2020) - Wireless coexistence
- ANSI IEEE C63.27-2017 - Wireless coexistence
- FCC testing per part 15

Human Factors Testing

Human Factors Validation testing was performed on the Withings BeamO to demonstrate the device is safe and effective for the intended users, uses and use environments as compared to the predicate. Testing was conducted per FDA guidance, "*Applying Human Factors and Usability Engineering to Medical Devices*". The study included simulated use scenarios and knowledge task questions. During the interview process, objective and subjective data was collected to help determine potential root causes of any use errors and difficulties related to the user interface. Participants were not given any formal training prior to using Withings BeamO beyond the information provided in the labeling.

Overall users were able to understand how they should take measurements with Withings BeamO, interpret the results, and understand when it is appropriate to seek medical help. Users were also able to answer simple and more complex questions around the warnings and precautions of the device. Users had a very good level of understanding of the usage of the device.

Bench Testing

Bench testing was performed with a reference device to validate the stethoscope function. For the temperature function, laboratory test was performed per "ISO 80601-2-56 Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement" and "*ASTM 1965-98 Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature*" to validate the performance of the subject device.

Clinical Testing

A first clinical study was conducted from June 3, 2024, to June 10, 2025, with the aim of validating the performance of the SCT02 ECG acquisition. A total of 382 patients - 190 in Normal Sinus Rhythm, 158 in Atrial Fibrillation, 24 Inconclusive, and 1 Uninterpretable - were enrolled in the study (refer to **table 2** for demographics of the patient population) and 630 ECGs were analyzed for duration, visibility, and polarity. The ECG waveform evaluation showed strong concordance between the Withings BeamO and the 12-lead ECG reference device, indicating the accuracy and reliability of the Withings device in capturing and interpreting ECG signals. The agreement of the P, QRS, and T-waves visibility and polarity (visibility between 97.9% and 100%, polarity between 95.2% and 100%). The agreement for PR, QRS and QT durations was 98.8%, 94.0%, and 94.2% (respectively) with an error ≤ 40 ms. These results demonstrate that the subject device is substantially equivalent to the predicate device.

Male	**240 (63%)**
Female	**142 (37%)**
Age (years)	**64.7 +/- 19.2**
Caucasian	**311 (81%)**
African American or Black	**45 (12%)**
Asian	**25 (7%)**
Other	**2 (0.6%)**
Hispanic or Latino	**78 (20%)**
Not Hispanic or Latino	**304 (80%)**
BMI (kg/m^2)	**27.4 +/- 5.0**

Table 2. Demographic characteristics of the clinical study population of the SCT02 ECG acquisition performance validation. For quantitative data, results are presented as mean +/- SD.

A second clinical accuracy study was conducted to validate the accuracy of the SCT02 BeamO thermometer in accordance with ISO 80601-2-56:2017, which provides requirements for the clinical thermometers used in healthcare. The device's performance was assessed relative to the predicate device, the Withings Thermo (SCT01). The study included a total of 106 subjects, that were distributed over age groups. The age groups (as specified by ISO 80601-2-56) distribution across the three age groups was as follows:

Demographics				
	FAS	PP	PP Afebrile	PP Febrile
Total Patients	105	96	73	23
Age Group				
0 to 3 months	15	12	12	0
3 months to 1 year	17	15	12	3
1 to 5 years	35	34	25	9
Older than 5 years	38	35	24	11

Table 3. Demographic of the SCT02 thermometer clinical accuracy study. FAS means Full Analysis Set and PP refers to Per Protocol.

The evaluation focused on the following metrics:

- Clinical Bias: -0.074°F, indicating that the BeamO measured slightly lower than the predicate device thermometer.
- Limits of Agreement: ±1.023°F.
- Repeatability: 0.29°F.

No adverse events or device malfunctions were reported during the study. The results demonstrate the accuracy of the Withings BeamO Smart Thermometer in measuring body temperature relative to the predicate device thermometer. While ISO 80601-2-56 does not establish specific acceptance criteria, the findings support the performance claims of the device

for its intended use. Based on the data provided, the Withings BeamO Smart Thermometer (SCT02) is as safe and effective as the predicate device (Withings Thermo SCT01) and complies with relevant regulatory standards.

8. Conclusion

The subject device is intended to record, display (when prescribed or used under the care of a physician), store and transfer single-channel electrocardiogram (ECG) rhythms same as the primary predicate device AliveCor Heart Monitor.

The subject device has two additional functions (temperature and stethoscope) that the primary predicate does not have.

The subject device and the secondary predicate device have the same intended use for the temperature feature. Both devices are intended for the intermittent determination of human body temperature over the temporal artery.

The subject device is also an electronic stethoscope intended for recording and transmission of auscultation sound data same as the secondary predicate device Tyto Stethoscope and reference device 1 Eko model E5.

Therefore, the intended use of the subject device, primary predicate device, secondary predicate and reference devices is the same.

The subject device uses the same technology (stainless steel ECG electrodes, infrared, and piezoelectric technology) as the primary predicate, secondary predicate and reference devices. The difference is that the subject device combines these technological characteristics onto a single device. However, this does not raise different questions of safety and effectiveness because non-clinical and clinical tests performed on the subject device per FDA recognized standards demonstrate equivalent performance as the primary and secondary predicates and reference devices.

Therefore, the subject device is substantially equivalent to the primary predicate, secondary predicates and reference devices.