August 23, 2023

Withings
Khushboo Surendran
Regulatory Affairs Manager
2 rue Maurice Hartmann
Issy-Les-Moulineaux, Ile-De-France 92130
France

Re: K230812
Trade/Device Name: Withings Scan Monitor 2.0
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS, DXH
Dated: July 21, 2023
Received: July 24, 2023

Dear Khushboo Surendran:

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); 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,

Jennifer W. Shih -S

Jennifer Shih 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

5. Indications for Use

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: June 30, 2023
See PRA Statement on last page

510(k) Number *(if known)*

Device Name

Withings Scan Monitor 2.0

Indications for Use *(Describe)*

The Withings Scan Monitor 2.0 is intended to record, store and transfer lead II and lead-III of a two-channel electrocardiogram (ECG). In addition, it calculates and displays leads I, aVR, aVF, aVL. The Withings Scan Monitor 2.0 also displays ECG rhythms and detects the presence of atrial fibrillation (when the monitor is prescribed or used under care of a physician).

The Withings Scan Monitor 2.0 is intended for use by healthcare professionals, patients with known or suspected heart conditions and health-conscious individuals.

The Withings Scan Monitor 2.0 is intended for adult patients in hospitals, clinics, long-term care facilities, and homes.

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

1. Submitter

Applicant:	Withings 2 Rue Maurice Hartmann Issy-Les-Moulineaux France 92130
Submission Correspondent:	Khushboo Surendran Regulatory Affairs Manager Phone: 857-233-2681 Email: khushboo.surendran@withings.com
Date Prepared:	March 23, 2023

2. Subject device Information

Device Name:	Withings Scan Monitor 2.0
Regulation name:	Electrocardiograph
Regulation number:	21 CFR 870.2340
Regulatory Class:	Class II
Product Code:	DPS, DXH
510(k) review panel:	Cardiovascular

3. Predicate device Information

Predicate Manufacturer:	Withings
Predicate device name:	Scan Monitor
Predicate 510(k) number:	K201456

4. Description of the device

The Withings Scan Monitor 2.0 is a connected smart scale with a retractable handle, with Bluetooth and Wi-Fi capabilities that connects to a companion mobile application. The Withings Scan Monitor 2.0 is intended to create, record, store, transfer and display lead-II and lead-III of a two-channel electrocardiogram (ECG).

When a user stands on the scale and holds the handle attached to it, a 30 second ECG recording begins. The Withings Scan Monitor 2.0 software analyzes data collected by the electrical sensors present on the scale to generate lead-II and lead-III simultaneously and derive lead-I and leads aVR, aVF and aVL, calculate heart rate, and provide a rhythm classification to the user that is displayed on the scale. The companion application is intended to display, store, manage and share data.

The Withings Scan Monitor 2.0 classifies ECG signals as follows:

- Normal Sinus Rhythm
- Atrial Fibrillation
- Inconclusive
- Noise - Inconclusive

5. Indications for Use/Intended Use:

The Withings Scan Monitor 2.0 is intended to record, store and transfer lead II and lead-III of a two-channel electrocardiogram (ECG). In addition, it calculates and displays leads I, aVR, aVF, aVL.The Withings Scan Monitor 2.0 also displays ECG rhythms and detects the presence of atrial fibrillation (when the monitor is prescribed or used under care of a physician).

The Withings Scan Monitor 2.0 is intended for use by healthcare professionals, patients with known or suspected heart conditions and health-conscious individuals.

The Withings Scan Monitor 2.0 is intended for adult patients in hospitals, clinics, long-term care facilities, and homes.

6. Comparison to the Predicate

Characteristics	Subject device: Withings Scan Monitor 2.0	Predicate device: Scan Monitor	Comparison to predicate device
Device Name	Withings Scan Monitor 2.0	Scan Monitor	NA
Number of leads	6-Lead	1-Lead	Substantially equivalent. The only minor difference is that the subject device records lead II and lead-III of a two-channel electrocardiogram (ECG) and calculates lead I, whereas the predicate device analyzes a single-channel ECG and displays only lead I ECG. **Both devices use ECG Lead I for rhythm classification assessment**. Lead II, lead III, aVR, aVF and aVL are for information purposes only and are validated in the clinical study against the gold standard (12 lead ECG).
Manufacturer	Withings	Withings	Identical
510(k)	K230812	K201456	NA
Regulation Number	21 CFR 870.2340 21 CFR 870.2920	21 CFR 870.2340 21 CFR 870.2920 21 CFR 870.2700	Identical, except for the regulation for oximeter which does not apply to the subject device
Class	II	II	Identical
510(k) Review Panel	Cardiovascular	Cardiovascular	Identical
Device Class/Name	Electrocardiograph Transmitters and Receivers, Electrocardiograph, Telephone	Electrocardiograph Transmitters and Receivers, Electrocardiograph, Telephone Oximeter	Identical, except that the predicate device can also measure oxygen saturation of arterial hemoglobin (%SpO2)

			and therefore is also an oximeter
Product Code	DPS, DXH	DPS, DXH, DQA	Identical, except that the predicate device can also measure oxygen saturation of arterial hemoglobin (%SpO2) and therefore has an additional product code (DQA)
Prescription / OTC	Prescription and OTC	Prescription and OTC	Identical for the ECG acquisition and the atrial fibrillation detection functionalities as Scan Monitor and Withings Scan Monitor 2.0.
Intended use and Indications for Use	The Withings Scan Monitor 2.0 is intended to record, store and transfer lead II and lead-III of a two-channel electrocardiogram (ECG). In addition, it calculates and displays leads I, aVR, aVF, aVL. The Withings Scan Monitor 2.0 also displays ECG rhythms and detects the presence of atrial fibrillation (when the monitor is prescribed or used under care of a physician). The Withings Scan Monitor 2.0 is intended for use by healthcare professionals, patients with known or suspected heart conditions and health-conscious individuals. The Withings Scan Monitor 2.0 is intended for adult patients in hospitals, clinics, long-term care facilities, and homes.	Scan Monitor is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The Scan Monitor also displays ECG rhythms and detects the presence of atrial fibrillation (when the monitor is prescribed or used under the care of a physician). The Scan Monitor is intended for use by healthcare professionals, patients with known or suspected heart conditions and health-conscious individuals. The Scan Monitor is also indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO2). The Scan Monitor is intended for adult patients in hospitals, clinics, long-term care facilities, and homes.	Substantially equivalent, The predicate device also allows for the measurement of oxygen saturation of arterial hemoglobin (%SpO2) with the predicate device. Both devices record, store and display ECGs.
Intended population	Adults with known or suspected heart conditions and health-conscious individuals	Adults with known or suspected heart conditions and health-conscious individuals	Identical
Environment Use	Hospitals, clinics, long term care and home use	Hospitals, clinics, long-term care and home use	Identical

Table 6-1: High-level comparison between the subject device (Withings Scan Monitor 2.0) and previously cleared device (Scan Monitor) for intended use, and indications of use.

Both devices are intended to record, store and transfer electrocardiogram (ECG) and display ECG rhythms and detect the presence of atrial fibrillation.

Both devices have a similar intended population, i.e. healthcare professionals, patients with known or suspected heart conditions, health-conscious individuals and adults.

Both devices are intended for adult patients in hospitals, clinics, long-term care facilities, and homes.

Both devices consist of the combination of the electromechanical assembly (Scan Watch for the predicate device and Body Scan for the subject device) and the related software brick included in the Health Mate companion app. For the ECG feature, both devices are intended to be used when prescribed or used under the care of a physician.

Technological Characteristic	Subject device: Withings Scan Monitor 2.0	Predicate device: Scan Monitor	Comparison to predicate device
Hardware Interface	Body Scan (scale)	Scan Watch (watch)	Substantially equivalent. Please refer to the bench testing and clinical study report that demonstrate substantially equivalent performance. Therefore, differences in hardware interface are substantially equivalent.
Principles of Operation	User completes the circuit with skin contact and hardware collects and transmits electrical potentials to the microcontroller unit to convert and display ECG waveform. After acquisition, the Withings Scan Monitor 2.0 uses the ECG waveforms from the Withings Body Scan, and the Withings Scan Monitor 2.0 algorithms process and classify the signal and display the classification to the user.	User completes the circuit with skin contact and hardware collects and transmits electrical potentials to the microcontroller unit to convert and display ECG waveform. After acquisition, the Scan Monitor uses the ECG waveforms from the Withings Scan Watch, and the Withings Scan Monitor 2.0 algorithms process and classify the signal and display the classification to the user.	Identical
Anatomical sites	Fingers and feet.	Left hand fingers to right wrist or vice versa	Substantially equivalent. The first main difference between the two devices is the site of ECG measurement. Please refer to the bench testing results that show that the subject device has lower RMSE distribution with a 12-lead ECG device than that of the predicate device and show that ECG waveforms of the predicate and subject devices are equivalent in terms of visibility of P-wave, T-wave, QRS complex visibility and polarity and durations. Therefore the anatomical site differences do not raise any issue of effectiveness in terms of ECG signal quality and also atrial fibrillation detection.
Acquisition position	Standing up on the device	Seated with arms rested on a table	Substantially equivalent. Please refer to the bench testing results that show that the subject device has lower RMSE distribution with a 12-lead ECG device than that of the predicate device and subject devices are equivalent in terms of visibility of P-wave, T-wave, QRS complex visibility and polarity and durations. Therefore the acquisition site difference does not raise any issue of effectiveness in terms of ECG signal quality and also atrial fibrillation detection.

Number of ECG measuring electrodes	Three ECG measuring electrodes	Two ECG measuring electrodes	Substantially equivalent. The second main difference between the two devices is the number and function of the ECG electrodes, resulting in the different number of leads. The subject device has three (3) ECG measuring electrodes that come in contact with left fingers, right fingers, left foot, whereas the predicate has two (2) ECG measuring electrodes that come in contact with the wrist.
Number of feedback electrodes	Two (2) feedback electrodes	One (1) feedback electrodes	Substantially equivalent.The subject device has two (2) feedback electrodes on the sole of the right foot serving as a feedback mechanism to eliminate environmental electromagnetic interference, whereas the predicate has one reference electrode that comes in contact with the fingers to eliminate environmental electromagnetic interference by a similar feedback mechanism.
ECG acquisition duration	30 seconds	30 seconds	Identical
Resolution	16 bits	16 bits	Identical
Sampling Rate	500Hz	300Hz	Substantially equivalent. The subject device has a higher sampling frequency that does not affect the performance of the ECG acquisition
Data storage	8 Mbytes	8 Mbytes	Identical
Analog Filter Bandwidth	0.033Hz - 200Hz	0.34 Hz - 52 Hz	Substantially equivalent. The subject device has a wider detection bandwidth that does not affect the performance of the ECG-SW1 AFib detection as the Equivalence between Withings Scan Monitor 2.0 and Withings Scan Monitor ECG Waveforms report concludes
ECG Classification Results	Normal Sinus Rhythm Atrial Fibrillation Inconclusive Noise	Normal Sinus Rhythm Atrial Fibrillation Inconclusive Noise	Identical
Location of signal processing	In the device	In the device	Identical
Firmware algorithm	ECG-SW1 algorithm	ECG-SW1 algorithm	Identical
Power Supply: Battery Battery Life (typical)	Rechargeable Lithium-ion battery	Rechargeable Lithium-ion battery	Identical
Degree of protection	Type BF- Applied parts	Type BF- Applied parts	Identical
Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-47 ANSI/AAMI EC57	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-47 ANSI/AAMI EC57	Identical

	AAMI TIR69:2017/(R2020) ANSI IEEE C63.27-2017 FCC testing per part 15	AAMI TIR69:2017/(R2020) ANSI IEEE C63.27-2017 FCC testing per part 15	
Display format	LCD screen 320 x 240 pixels	OLED screen 116 x 80 pixels	Substantially equivalent, no impact on the display. Bigger screen on the subject device for the 6-lead display
Physical Specs: Dimensions Weight	372 x 446 x 45 mm 4.4 kg	240 x 38.4 x 13.2 mm 0.058 kg	Substantially equivalent. The subject device is bigger than the predicate device allowing it to have bigger electrodes and therefore more reliable ECG signal acquisitions.
Environmental: Operating Temp Storage	Operating: +5°C to 35°C Storage: -10°C to 50°C	Operating: +5°C to 40°C Storage: -20°C to 70°C	Substantially equivalent
Communications, Companion Mobile Application	Setup in BLE Scale used via WIFI and BLE	Setup in BLE Watch used via BLE	Substantially equivalent

Table 6-2: High-level comparison between the subject device (Withings Scan Monitor 2.0) and previously cleared device (Scan Monitor) for technological characteristics.

At a high level, the subject device records a two channel ECG utilizing three electrodes on the smart scale that can then be transferred and displayed to the user or healthcare professional on the companion mobile application. Similarly, the predicate device records a single channel ECG using three electrodes on the smart watch and displays the results on a companion mobile application.

The subject device has the same intended use and indications for use as the predicate device including the intended use population and intended use environment. Both devices are intended to record, store and transfer electrocardiogram (ECG) and display ECG rhythms and detect the presence of atrial fibrillation. Minor differences in the number of leads is intended to provide additional information but does not affect the substantial equivalence of the device and does not alter the intended clinical application.

The fundamental technology of using stainless steel electrodes to measure ECG and detect atrial fibrillation is the same for the subject device and the predicate device. The minor technical differences do not raise different questions of safety and effectiveness because the non clinical testing, usability testing and clinical testing demonstrate equivalent device performance as the predicate device.

7. Summary of Performance Testing

Non Clinical Testing

All necessary performance testings were conducted on the subject device to support a determination of substantial equivalence to the predicate device. This testing included testing to the following standards:

- IEC 60601-1:2005, ANSI AAMI ES60601-1:2005/A2:2021 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 60601-2-47:2012 Medical Electrical Equipment – Part 2-47: Particular Requirements For The Basic Safety And Essential Performance Of Ambulatory Electrocardiographic Systems.
- 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.
- ANSI/AAMI EC57: Testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms.
- AAMI TIR69:2017/(R2020) - Technical Information Report Risk management of radio-frequency, wireless coexistence for medical devices and systems
- ANSI IEEE C63.27-2017 - American National Standard for Evaluation of Wireless Coexistence
- FCC testing per part 15

The device was tested for cytotoxicity, sensitization, irritation and intracutaneous irritation as per according to "Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process", 2020.

Software verification and validation was performed per FDA guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". The software for Withings Scan Monitor 2.0 is considered to have a "moderate" level of concern.

Human Factors Testing

Human Factors Validation testing was performed on the Withing Scan Monitor 2.0 to demonstrate substantial equivalence for the intended users, uses and use environments. Testing was conducted per FDA guidance "Applying Human Factors and Usability Engineering to Medical Devices". The Human Factor Validation study was performed in the U.S. with US participants and was conducted with 2 user groups:

1. Adult lay users of ages 22-64 years, and
2. Elderly lay users of ages 65+ years

Both user groups included participants who are a mix of lay users with and without AFib.
The validation protocol included simulated use scenarios, critical knowledge task questions, and interview questions to collect objective and subjective data to help determine potential root causes of any use errors and difficulties related to the user interface.

Users demonstrated a very good level of understanding and usage of the product. Overall users were able to record the ECG measurements, interpret the results and understand when it is appropriate to seek medical help. They were also able to answer simple and more complex questions around the contraindications and warnings of the product.

Algorithm Testing

Three distinct sets of data were used to design the algorithm. Each dataset is used in one of the usual three stages of a robust Machine Learning algorithm development: training, testing, and validation of the final ("locked") algorithm. In order to prevent any data leak or overfitting, there is no overlap between these three datasets. In particular, the data used for validation is independent from any training or testing since the recordings come from separate, independent sources: devices, patients, ECG reviewers and centers were all different.

Publicly available datasets were utilized for the training dataset. The testing datasets consist of several smaller datasets. A summary of the demographic characteristics of the test data set is provided in the table below:

Test Data Set 1 (n=137)			*Test Data Set 2 (n=262)*		
Demographic Characteristics			*Demographic Characteristics*		
Age			*Age*		
66.6 +/- 13.5			*68.2 +/- 14.8*		
Sex			*Sex*		
	(N)	*(%)*		*(N)*	*(%)*
Male	*81*	*59*	*Male*	*160*	*61*
Female	*56*	*41*	*Female*	*102*	*39*
BMI (kg/m^2)			*BMI (kg/m^2)*		
27.8 +/- 5.9			*27.5 +/- 5.7*		
Height (cm)			*Height (cm)*		
169.1 +/- 10.1			*169.2 +/- 9.2*		
Weight (kg)			*Weight (kg)*		
81.3 +/- 20.7			*78.9 +/- 17.6*		
Cardiovascular Risk Factors			*Cardiovascular Risk Factors*		
Hypertension			*Hypertension*		
59/137 (43%)			*135/262 (52%)*		
Dyslipidemia			*Dyslipidemia*		
29/137 (21%)			*90/262 (34%)*		
Overweight or Obesity			*Overweight or Obesity*		
75/137 (55%)			*111/262 (42%)*		
Diabetes			*Diabetes*		
16/137 (22%)			*57/262 (22%)*		

Table 6-3: Demographic Characteristics of the ECG-SW1 algorithm test data set.

Clinical Study

The clinical study was a prospective, cross-sectional, diagnostic, multicentric open-label study with the anticipated total number of subjects that were planned to be recruited to meet the target was 250 patients of which 125 subjects with a known diagnosis of AF and 125 subjects with a known diagnosis of SR. The purpose of the study was to validate a rhythm classification algorithm ECG-SW1 running on the subject device Withings Scan Monitor 2.0 (WBSSM2) and its ability to detect and classify heart rhythms into one of four categories (sinus rhythm (SR), atrial fibrillation (AF), inconclusive or noise) using a six-lead ECG strip and to validate the Withings Scan Monitor 2.0 (WBSSM2) ability to generate a 6-lead electrocardiogram (ECG) that is clinically equivalent to a standard 12-lead ECG. 274 patients were included in the present study. 40 patients had to be excluded from the data analysis. Withings Scan Monitor 2.0 (WBSSM2) classified as “noise” 7.7% of the valid ECG records (25/321). Of the remaining signals (at rest + after effort), excluding other arrhythmias, Withings Scan Monitor 2.0 (WBSSM2) reached a sensitivity of 0.99 with a 95% confidence interval of [0.93, 1.0] and a specificity of 0.99 with a 95% confidence interval of [0.97, 1.0]. Withings Scan Monitor 2.0 (WBSSM2) accuracies computed on the visibility of all ECG waves (P-waves, QRS complexes and T-waves) was above 0.992. Polarity accuracy was 0.986 for P-waves, 0.948 for QRS complex, and 0.911 for T-waves. The standard deviation of the differences of duration of PR interval and QRS width between the signals of Withings Scan Monitor 2.0 (WBSSM2) and the 12-lead gold standard ECG device was < 20 ms, that is less than half the length of the smallest graduation on a standard paper ECG trace. The standard deviation of differences of duration of QT intervals was 30.3ms. Finally, the mean difference between heart rate measured by Withings Scan Monitor 2.0 (WBSSM2) and heart rate measured on the 12-lead ECG was -0.96 bpm with a 3.81 bpm standard deviation (“noise” ECGs excluded). The standard deviation of 3.81 bpm, being below the acceptable threshold for heart rate measurements error of 10%.

The table below presents the full confusion matrix for the subject device performance including all 4 outputs.

Withings Clinical Study (321 participants)		**12-lead Reference ECG signals reviewed by cardiologists**				
		Normal Sinus Rhythm	**Atrial Fibrillation**	**Inconclusive**	**Noise**	**TOTAL**
6-lead Withings Scan Monitor 2.0	**Normal Sinus Rhythm**	170	1	9	5	185
	Atrial Fibrillation	1	74	0	2	77
	Inconclusive	4	8	21	1	34
	Noise - Inconclusive	3	18	2	2	25
	TOTAL	178	101	32	10	**321**

Table 6-4: Confusion matrix for Withings Scan Monitor 2.0 Vs 12-lead Reference ECG classification reviewed by cardiologists

Performance Comparison to predicate device

The table below provides the performance for the Withings Scan Monitor 2.0 compared to the

predicate device (Withings Scan Monitor).

Atrial Fibrillation /Normal Sinus Rhythm	Withings Scan Monitor 2.0	Withings Scan Monitor
Sensitivity [95% confidence interval lower bound]	0.73 [0.639]	0.77 [0.675]
Specificity [95% confidence interval lower bound]	0.955 [0.914]	0.965 [0.912]
Sensitivity AF/NSR only [95% confidence interval lower bound] ("Inconclusive" and "noise" excluded.)	0.989 [0.928]	0.963 [0.894]
Specificity AF/NSR only [95% confidence interval lower bound] ("Inconclusive" and "noise" excluded.)	0.994 [0.968]	1.000 [0.967]

Table 6-5: Performance for the Withings Scan Monitor 2.0 compared to the predicate device

The sensitivity of Withings Scan Monitor was estimated to be 77% (lower bound 95%CI=67.5%) whereas the sensitivity of the Withings Scan Monitor 2.0 was 73.3% (lower bound 95%CI=63.9%). Although there are differences in sensitivities between the two devices, both devices have equivalent performance because both devices use the same algorithm and meet the confidence intervals criteria and the difference in terms of sensitivity is not statistically significant.

8. Conclusion

The Withings Scan Monitor 2.0 has similar intended use and technological characteristics as the predicate device. Differences in technological characteristics were assessed through performance testing to show that the differences do not raise different questions of safety and effectiveness compared to the predicate device. Software verification and validation, Non-clinical testing, human factors and clinical study data demonstrate that the Withings Scan Monitor 2.0 is substantially equivalent to the predicate device.