November 4, 2021

Microlife Intellectual Property GmbH
% Vaibhav Rajal
Official Correspondent for Microlife Intellectual Property GmbH
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, New York 11021

Re: K211288
Trade/Device Name: Microlife Wrist Watch Blood Pressure Monitor Model BP3GK1-4B
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: September 28, 2021
Received: October 6, 2021

Dear Vaibhav Rajal:

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,

for

LCDR Stephen Browning
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211288

Device Name
Microlife Wrist Watch Blood Pressure Monitor, Model BP3GK1-4B

Indications for Use *(Describe)*
The Wrist Watch Blood Pressure Monitor, Model BP3GK1-4B is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable cuff is wrapped around the wrist for a circumference range from 13.5 to 21.5cm. The device detects the appearance of irregular heartbeat during measurement and gives a warning signal with the reading once the irregular heartbeat is detected.
The device can be used in connection with a smart phone running the APP. The memory data can be transferred to the smart phone via Bluetooth.

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.

510(k) SUMMARY

The assigned 510(k) number is K211288

1. Submitter's Identification:

Microlife Intellectual Property GmbH, Switzerland
Espenstrasse 139
9443 Widnau / Switzerland

Date Summary Prepared: November 2, 2021

Contact: Mr. Gerhard Frick
Vice President of Technical and Service
Microlife Intellectual Property GmbH, Switzerland
Tel: +41 79 216 0070
E-Mail: gerhard.frick@microlife.ch

2. Name of the Device:

Microlife Wrist Watch Blood Pressure Monitor, Model BP3GK1-4B

Regulation Number: 21 CFR Part 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: II
Product Code: DXN

3. Information for the 510(k) Cleared Device (Predicate Device):

1) Microlife Wrist Watch Blood Pressure Monitor, Model BP3NN1-3E, K151330, Microlife Intellectual Property GmbH.
2) Omron Wrist Blood Pressure Monitor Model BP4350, K182166, Omron Healthcare, Inc.

4. Device Description:

Microlife Wrist Watch Blood Pressure Monitor, Model BP3GK1-4B is designed to measure systolic and diastolic blood pressure and pulse rate of an individual by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist. Our method to define systolic and diastolic pressure is similar to the auscultatory method but uses a semiconductor sensor rather than a stethoscope and mercury manometer. The sensor converts tiny alterations in cuff pressure to electrical signals, by analyzing those signals to define the systolic and diastolic blood pressure and calculating pulse rate, which is a well - known technique in the market called the “oscillometric method”.

The device detects the appearance of irregular heartbeat during measurement. In addition, the device can be used in connection with smart mobile devices running the APP and via Bluetooth.

5. Indications for Use:

The Wrist Watch Blood Pressure Monitor, Model BP3GK1-4B is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable cuff is wrapped around the wrist for a circumference range from 13.5 to 21.5cm. The device

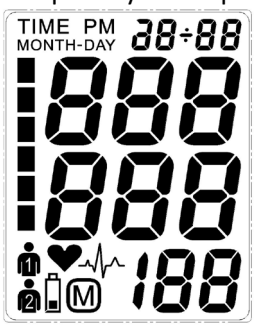
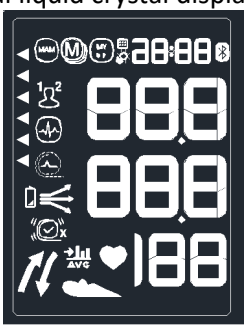
detects the appearance of irregular heartbeat during measurement and gives a warning signal with the reading once the irregular heartbeat is detected.

The device can be used in connection with a smart phone running the APP. The memory data can be transferred to the smart phone via Bluetooth.

6. Comparison to the 510(k) Cleared Device (Predicate Device):

Microlife Wrist Watch Blood Pressure Monitor BP3GK1-4B has been compared to the "Microlife Wrist Watch Blood Pressure Monitor BP3NN1-3E, K151330" & "Omron Wrist Blood Pressure Monitor BP4350, K182166" as reference for substantial equivalence. A table comparing the predicate device to the subject device, BP3GK1-4B, is shown as the following:

Item	**Predicate device No.1: Microlife Wrist Watch BPM BP3NN1-3E, Microlife Intellectual Property GmbH K151330**	**Predicate device No.2: Omron Wrist Blood Pressure Monitor Model BP4350, Omron Healthcare, Inc. K182166**	**Modified device: Microlife Wrist Watch BPM BP3GK1-4B, Microlife Intellectual Property GmbH**	**Similar or Different**
Indications for Use	The Wrist Watch Blood Pressure Monitor, Model BP3NN1-3E is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable cuff is wrapped around the wrist for a circumference range from 13.5 to 21.5cm. The device detects the appearance of irregular heartbeat during measurement and gives a warning signal with the reading once the irregular heartbeat is detected.	The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 5.3 inches to 8.5 inches (13.5cm to 21.5cm). The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.	The Wrist Watch Blood Pressure Monitor, Model BP3GK1-4B is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable cuff is wrapped around the wrist for a circumference range from 13.5 to 21.5cm. The device detects the appearance of irregular heartbeat during measurement and gives a warning signal with the reading once the irregular heartbeat is detected. The device can be used in connection with a smart phone running the APP. The memory data can be transferred to the smart phone via Bluetooth.	Similar
Device Technology	Oscillometric method	Oscillometric method	Oscillometric method	identical
Measuring Location	Wrist	Wrist	Wrist	identical

Appearance (ID design)				different
Item	**Predicate device No.1: Microlife Wrist Watch BPM BP3NN1-3E, Microlife Intellectual Property GmbH K151330**	**Predicate device No.2: Omron Wrist Blood Pressure Monitor Model BP4350, Omron Healthcare, Inc. K182166**	**Modified device: Microlife Wrist Watch BPM BP3GK1-4B, Microlife Intellectual Property GmbH**	**Similar or Different**
Microprocessor	MB95F718J 1. Fujitsu MCU core 2. Main clock frequency: 8 MHz 3. Sub clock frequency: 32.768 kHz 4. System voltage level: 3.3V 5. Pressure sensor type: Semiconductor sensor 6. The amount of MCU pins: 80 pins	N/A	HY16F198B 1. HYCOM MCU core 2. Main clock frequency: 8 MHz 3. Sub clock frequency: 32.768 kHz 4. System voltage level: 3.3V 5. Pressure sensor type: Semiconductor sensor 6. The amount of MCU pins: 100 pins	different
Sensor	Semiconductor sensor	Semiconductor sensor	Semiconductor sensor	identical
F/W reversion of Algorithm	FK5 1. Blood pressure algorithm: Wrist for inflation measurement 2. Signal filter: FIR filter 3. Algorithm: Oscillometric measurement 4. Irregular heart beat detection: IHD	N/A	yi2 1. Blood pressure algorithm: Wrist for inflation measurement 2. Signal filter: FIR filter 3. Algorithm: Oscillometric measurement 4. Irregular heart beat detection: IHD	different
Signal Detection Technology	Detect electrical signals while inflating (called “IMT“ technology)	Detect electrical signals while inflating	Detect electrical signals while inflating (called “IMT“ technology)	identical
Display	Digital liquid crystal display 	Digital liquid crystal display 	Digital liquid crystal display 	different

Pressure and Pulse Rate Accuracy	Pressure within ± 3 mmHg or 2% of reading >200mmHg Pulse ± 5 % of the reading	Pressure within ± 3 mmHg Pulse ± 5 % of the reading	Pressure within ± 3 mmHg or 2% of reading >200mmHg Pulse ± 5 % of the reading	identical to No.1
Item	**Predicate device No.1: Microlife Wrist Watch BPM BP3NN1-3E, Microlife Intellectual Property GmbH K151330**	**Predicate device No.2: Omron Wrist Blood Pressure Monitor Model BP4350, Omron Healthcare, Inc. K182166**	**Modified device: Microlife Wrist Watch BPM BP3GK1-4B, Microlife Intellectual Property GmbH**	**Similar or Different**
Measuring Range	SYS/DIA: 30 to 280 mmHg Pulse: 40 to 200 per minutes	SYS: 60 to 260 mmHg DIA: 40 to 215 mmHg Pulse: 40 to 180 per minutes	SYS: 60-255 mmHg DIA: 40-200 mmHg 40 to 199 per minute	different
Pressure Resolution	1mmHg	1mmHg	1mmHg	identical
Cuff Display Range	0 to 299mmHg	0 to 299mmHg	0 to 299mmHg	identical
Power Source	2 Batteries, size AAA 1.5V	2 Batteries, size AAA 1.5V	2 Batteries, size AAA 1.5V	identical
Low Battery Voltage Detection	Yes	Yes	Yes	identical
User	2	2	2	identical
Last Measurement Recall	2*60 sets	2*100 sets	2*100 sets	identical to No.2
Beeper Indication	Yes	No	Yes	identical to No.1
Irregular Heartbeat Detection Function	Yes	Yes	Yes	identical
Traffic Light Function	Yes	Yes (Hypertension Indicator)	Yes	identical
MAM function	No	No	Yes	different
Wrist Position Check function	No	Yes (Heart Zone Indicator)	Yes	identical to No.2
Cuff fit check function	No	Yes (Cuff Wrap Guide)	Yes	different
MyCheck function	No	No	Yes	different
MyBP function	No	No	Yes	different
AM/PM Average Stored Function	No	Yes (Morning Averages)	Yes	different
Bluetooth function	No	Yes	Yes Using Bluetooth(4.2)	identical to No.2
Item	**Predicate device No.1: Microlife Wrist Watch BPM BP3NN1-3E, Microlife Intellectual**	**Predicate device No.2: Omron Wrist Blood Pressure Monitor Model BP4350, Omron Healthcare, Inc.**	**Modified device: Microlife Wrist Watch BPM BP3GK1-4B, Microlife Intellectual Property**	**Similar or Different**

	Property GmbH K151330	**K182166**	**GmbH**	
Operation Range	+10℃to +40℃at RH 15% to 90%	+10℃to +40℃at RH 15% to 90%	+10℃to +40℃at RH 15% to 90%	identical
Storage Range	-20℃to +55℃at RH 15% to 90%	-20℃to +60℃at RH 10% to 90%	-20℃to +55℃at RH 15% to 90%	identical to No.1
Life Time	At least 10000 times of operation	5 years	At least 10000 times of operation	identical to No.1
Cuff material	Flannelette cuff cloth PVC bladder		Flannelette cuff cloth PVC bladder	identical to No.1
Accessories	**Necessary :** Cuff for wrist circumference 13.5-21.5cm AAA batteries Instruction manual Gift box	**Necessary :** Cuff for wrist circumference 13.5-21.5cm AAA batteries Instruction manual Gift box	**Necessary :** Cuff for wrist circumference 13.5-21.5cm AAA batteries Instruction manual Gift box	Similar

The subject (Modified) device BP3GK1-4B uses the same oscillometric method as the predicate device No.1 BP3NN1-3E with the same fundamental scientific technology to determine the systolic and diastolic blood pressure and pulse rate. Wrist cuff is inflated automatically by pump and the pressures are transferred via tubing to a sensor in these two units. The Wrist Position Check function is identical technology to predicate device No.2 Omron BP4350 with an accelerometer to measure the angle of the arm in relation to the table.

The subject (Modified) device No.1 BP3GK1-4B and the predicate device BP3NN1-3E both have traffic light function, IHD function, and IMT technology. The differences between the devices are:

1. Indications for Use

The subject device BP3GK1-4B and predicate device BP3NN1-3E both are intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive oscillometric technique. The differences between subject device and predicate device both are the bluetooth function and wrist circumference. The subject device can be used in connection with a smart phone running the APP and the memory data can be transferred to the smart phone via Bluetooth. However, this function is only a way to transfer the data and does not affect the effectiveness and safety. It does not affect the effectiveness according to the essential performance testing.

2. Physical Dimension

The physical dimension of the subject device BP3GK1-4B is 81 x 65 x 21mm, while predicate device BP3NN1-3E is 75 x 63 x 20mm. The difference is caused because of their different appearance, but the difference does not raise any new safety and effectiveness questions. This has been tested and confirmed according to IEC 60601-1-2 EMC Test Report, IEC 60601-1, AAMIANSI ES60601-1 Safety Test Report and IEC 80601-2-30 Test Report.

3. Microprocessor

The microprocessor of the subject device BP3GK1-4B is HY16F198B, whereas the microprocessor of the predicate device BP3NN1-3E is MB95F718J. Their calculation algorithms are the same. But the amount of MCU pins is different. It does not affect performance and accuracy which was evaluated in the performance testing.

4. Algorithm

The algorithm of subject device BP3GK1-4B is yi2, while predicate device BP3NN1-3E is FK5. The only difference is the algorithm version, because these two models have different microprocessor. However, their calculation algorithm is the same. It does not affect performance and accuracy which was evaluated in the performance testing.

5. Display

The subject device BP3GK1-4B and predicate device BP3NN1-3E both have digital liquid crystal display. The only difference is the UI, because these two models have different ID design. It does not affect the effectiveness according to the essential performance testing.

6. Measuring Range

The measurement range between the subject (Modified) device BP3GK1-4B and the predicate device BP3NN1-3E is different. The subject device has a smaller measuring range. This does not affect the effectiveness according to the essential performance testing. It does not introduce any new risk to the device.

7. Last Measurement Recall

The subject device BP3GK1-4B can store 100 results per a user, while the predicate device BP3NN1-3E can store 60 results per a user. The subject device just has a greater storage capacity, so this doesn't affect the clinical test.

8. MAM function

The subject device BP3GK1-4B has the MAM function, whereas the predicate device BP3NN1-3E does not have the function. The MAM function is to give a simple average result based on three measurements are taken. This function is based on the measured results, so this doesn't affect the clinical test.

9. Wrist Position Check function

The subject device BP3GK1-4B has the Wrist Position Check function, whereas the predicate device BP3NN1-3E does not have the function. This function will be compared with predicate device No.2 Omron BP4350 in following section.

10. Cuff fit check function

The subject device BP3GK1-4B has the cuff fit check function, whereas the predicate device BP3NN1-3E does not have the function. The cuff fit check function is to check pulse strength during measurement, and indicates if pulse strength is OK. If pulse is too weak, nothing is indicated. This function is just a reference for properly wearing the cuff and does not affect the accuracy and efficacy of the use according to the clinical and essential performance testing, so it does not affect the safety or effectiveness.

11. AM/PM Average Stored Function

The subject device BP3GK1-4B has the AM/PM average stored function, whereas the predicate device BP3NN1-3E does not have the function. The AM/PM average stored function is to give an average result based on AM or PM measurements are taken. This function is based on the measured data, so this doesn't affect the clinical test.

12. MyCheck function

The subject device BP3GK1-4B has the MyCheck function, whereas the predicate device BP3NN1-3E does not have the function. The MyCheck function is to compare the systolic & diastolic blood pressure values from current measurement to the average of Systole & Diastole values in memory from the past 28 days. This function is based on the measured data, so this doesn't affect the clinical test.

13. MyBP function

The subject device BP3GK1-4B has the MyBP function, whereas the predicate device BP3NN1-3E does not have the function. The MyBP function is to take blood pressure values from mornings and evenings of a period between 3 and 7 days (depending on number of measurements taken) to provide an average blood pressure level. This function is based on the measured data, so this doesn't affect the clinical test.

14. Bluetooth function

The subject device BP3GK1-4B has the Bluetooth function, whereas the predicate device BP3NN1-3E does not have the function. This function is only a way to transfer the data and is based on the measured data, so it does not affect effectiveness and safety according to the performance testing and safety testing.

15. Accessories

The subject (Modified) device BP3GK1-4B and the predicate device No.2 Omron BP4350 both have Wrist Position Check function. The only difference of this feature between the devices is the symbols displayed on LCD screen. The acceptable range of angle of the arm in relation to the table and the instruction in IFU between two devices are identical.

Based upon the aforementioned information, the subject (Modified) device BP3GK1-4B and predicate device No.1 BP3NN1-3E & device No.2 Omron BP4350 are substantially equivalent.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Testing information demonstrating safety and effectiveness of the Microlife Wrist Watch Blood Pressure Monitor, Model BP3GK1-4B in the intended environment of use is supported by testing that was conducted in accordance with the FDA November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", DCRND, which outlines Electrical, Mechanical and Environmental Performance requirements.

The following testing was conducted to prove safety and effectiveness as well as substantial equivalence to the predicate device:

The following National and International Standards were utilized for testing the subject device:

1) IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance AAMI / ANSI ES60601-1:2005/(R) 2012 And A1:2012, C1:2009/(R) 2012 And A2:2010/(R) 2012

2) IEC 60601-1-2:2014 Medical electrical equipment Part 1-2: General requirements for safety and essential performance – Collateral standard: Electromagnetic Disturbances - Requirements And Tests.

3) ISO 14971: 2007 Medical devices – Application of risk management of medical devices.

4) AAMI/ANSI/ISO 10993-1:2018, Biological evaluation of medical devices – Part 1: Evaluation And Testing Within A Risk Management Process.

5) AAMI/ANSI/ISO 10993-5:2009/(R)2014, Biological evaluation of medical devices – Part 5: Tests for In Vitro Cytotoxicity.

6) AAMI / ANSI / ISO 10993-10:2010/(R)2014, Biological evaluation of medical devices – Part 10: Tests for Irritation and Skin Sensitization

7) AAMI/ANSI/ISO 10993-12: 2012, Biological evaluation of medical devices - Part 12: Sample preparation and reference materials

8) AAMI/ANSI/IEC 80601-2-30 Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers, 2013

9) IEC 60601-1-11:2015 Medical Electrical Equipment - Part 1-11: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment And Medical

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was our conclusion that Microlife Wrist Watch Blood Pressure Monitor, Model BP3GK1-4B tested met all relevant requirements of the aforementioned tests.

8. Discussion of Clinical Tests Performed:

From a clinical validation standpoint, the subject device is identical to the 510(k) cleared predicate device, BP3NN1-3E, K151330, in blood pressure measurement.

Regarding clinical validation concerning the compliance of ANSI/AAMI/IEC 81060-2, the subject blood pressure monitor Model BP3GK1-4B is from a technical point of view, identical to the predicate blood pressure monitor Model BP3NN1-3E.

The subject device BP3GK1-4B and the predicate device BP3NN1-3E both intended to measure systolic and diastolic blood pressures, pulse rate for use in an adult. And they both detect the appearance of irregular heartbeat during measurement and give a warning signal with the reading once the irregular heartbeat is detected.

The differences between the two models are addressed in VOL 5, 001 Comparison Chart. According to the information from the comparison chart, all the differences listed in the comparison chart do not affect the accuracy and normal use of this device because they use the same firmware of algorithm and fundamental scientific technology. Therefore the performance of BP3GK1-4B in terms of blood pressure measurement would be essential equivalent with performance of the predicate device BP3NN1-3E. There was no repeated clinical testing required for blood pressure measurement to support BP3GK1-4B as the subject device can leverage the clinical validation of BP3NN1-3E that was proven in K151330. Repeat clinical testing in accordance with the standard AAMI / ANSI/IEC81060-2 for the subject device BP3GK1-4B regarding blood pressure measurement for use in adults is therefore not warranted.

9. Software information:

Software validation was conducted in accordance with a moderate level of concern designation in accordance with the FDA November 2005 document “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”.

10. Conclusions:

Conclusions drawn from the non-clinical and clinical tests demonstrate that the subject device is as safe, effective, and performs as well as the predicate device.