October 28, 2026

Jiangsu Yuyue Medical Equipment & Supply Co., Ltd.
Zhang Fang (Fawn)
Director of Regulatory and Compliance
Jiangsu Yuyue Medical Equipment& Supply Co., Ltd.
#1 Baisheng Rd. Development Zone, Danyang, Jiangsu 212300 China
Danyang, Jiangsu 212300
China

Re: K260670
Trade/Device Name: YUWELL® Electronic Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: September 30, 2026
Received: September 30, 2026

Dear Zhang Fang (Fawn):

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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

Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

STEPHEN C. BROWNING -S

CDR 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260670

Device Name
YUWELL® Electronic Blood Pressure Monitor

Indications for Use *(Describe)*
This device is intended to measure blood pressure and pulse rate in patients over 12 years old with a wrist circumference ranging from 4.92 in to 8.46 in (12.5 cm to 21.5 cm) in households or medical centers. It is not suitable for neonates, pregnant individuals, or patients with pre-eclampsia.

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

Applicant/Sponsor Information

Applicant	**:**	JIANGSU YUYUE MEDICAL EQUIPMENT & SUPPLY CO., LTD.
Address	**:**	No.1 Baisheng Road Development Zone, Danyang, Jiangsu 212300 CHINA
Manufacturing Facility	**:**	No.1 Baisheng Road Development Zone, Danyang, Jiangsu 212300 CHINA
Contact of Correspondent	**:**	Fang (Fawn) Zhang
Phone	**:**	(206) 639-1311
Email	**:**	fawn.zhang@yuwell.com

Trade Name, Common Name, Classification

Trade Name	**:**	YUWELL® Electronic Blood Pressure Monitor
Common Name	**:**	YUWELL® Electronic Blood Pressure Monitor
Classification Name	**:**	System, Measurement, Blood-pressure, Non-invasive
Product Code	**:**	DXN
Regulation Number	**:**	21 CFR 870.1130
Device Class	**:**	2

Identification of Predicate Device

The identification of predicates within this submission is as follows:

Manufacturer	**:**	Omron Healthcare, Inc.
Trade Name	**:**	Wrist Blood Pressure Monitor Model BP4350
Common Name	**:**	Wrist Blood Pressure Monitor Model BP4350
Classification Name	**:**	System, Measurement, Blood-pressure, Non-invasive
Product Code	**:**	DXN
Regulation Number	**:**	21 CFR 870.1130
Device Class	**:**	2
FDA 510 (k) #	**:**	K182166

Description of the Device

YUWELL® Electronic Blood Pressure Monitor is a battery-powered, automatic, noninvasive, wrist blood pressure measuring system intended for over-the-counter (OTC) use. It is designed for wrist circumference ranging from 4.92 in to 8.46 in (12.5 cm to 21.5 cm). The systolic and diastolic blood pressures are measured using the oscillometric method, where the cuff is

inflated with an air pump and it deflates via an exhaust valve. During inflation, the cuff pressure is monitored, and the pulse waveform is captured. The pulse waveform is then further analyzed by a software, which determines the pulse rate, as well as the systolic and diastolic blood pressures.

Proposed Indications for Use

This device is intended to measure blood pressure and pulse rate in patients over 12 years old with a wrist circumference ranging from 4.92 in to 8.46 in (12.5 cm to 21.5 cm) in households or medical centers. It is not suitable for neonates, pregnant individuals, or patients with pre-eclampsia.

Technological Characteristics

The YUWELL® Electronic Blood Pressure Monitors are intended for medical professionals and lay persons to use at healthcare facilities or at home. The device applies the oscillometric method for blood pressure and pulse rate measurements. The device has multiple auxiliary functions for accurate measurement and convenient operation, such as indication for movement error, indication for irregular heartbeat (IHB), detection for cuff wearing, recorded measurement results check, display unit setting, display time and date setting, voice broadcast (optional), Bluetooth transmission (optional), etc.

Here, irregular heartbeat (IHB) means more than two pulse waves are identified where the instantaneous heart rate exceeds the average heart rate by 25% during blood pressure measurement. When an IHB detected, it indicates that the measurement results may be inaccurate. The device's IHB feature serves only as a signal quality indicator for potentially inaccurate measurements and the device is not indicated for patients with Arrhythmias.

Substantial Equivalence

Comparison of technological characteristics:

Elements of Comparison	Subject Device	Predicate Device	Comparison
Manufacture	JIANGSU YUYUE MEDICAL EQUIPMENT & SUPPLY CO., LTD.	Omron Healthcare, Inc.	/
Device Name	YUWELL® Electronic Blood Pressure Monitor	Wrist Blood Pressure Monitor Model BP4350	/
Model	YE8100B	BP4350	/
510(k)	-	K182166	/
Regulation	21 CFR 870.1130	21 CFR 870.1130	Same
Product Code	DXN	DXN	Same

Elements of Comparison	Subject Device	Predicate Device	Comparison
Classification	Class II	Class II	Same
Intended Use/Indication for Use	This device is intended to measure blood pressure and pulse rate in patients over 12 years old with a wrist circumference ranging from 4.92 in to 8.46 in (12.5 cm to 21.5 cm) in households or medical centers. It is not suitable for neonates, pregnant individuals, or patients with pre-eclampsia.	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 (13.5 cm to 21.5 cm). The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.	Note No.1
Patient Population	Patients who are more than 12 years old. The device is not suitable for neonates, pregnant individuals, or patients with pre-eclampsia.	Adults	Note No.2
Environment of Use	Household or medical center	Home	Note No.3
Performance			
Principle of Operation	Oscillometric method	Cuff oscillation method	Same
Measurement Site	Wrist	Wrist	Same
Measurement Range	• Pressure range: 0~300 mmHg • Pulse rate: 40~200 beats/min • Diastolic: 40-210 mmHg • Systolic: 60~260 mmHg	• Pressure range: 0~299 mmHg • Pulse rate: 40~180 beats/min • Diastolic: 40-215 mmHg • Systolic: 60~260 mmHg	Note No.4
Pressure Sensor	Semiconductor pressure	Semiconductor pressure	Same

Elements of Comparison	Subject Device	Predicate Device	Comparison
	sensor	sensor	
Applicable Cuff (Wrist Circumference)	12.5~21.5 cm	13.5~21.5 cm	Note No.5
Accuracy of Pressure Indicator	Within ±3 mmHg	Within ±3 mmHg	Same
Accuracy of Pulse Rate	Within ±5% of reading	Within ±5% of reading	Same
Inflation Method	Automatic inflation with piezoelectric pump	Automatic inflation with piezoelectric pump	Same
Deflation Method	Automatic rapid deflation value	Automatic rapid deflation value	Same
Display	LCD digital display	LCD digital display	Same
Power source	2 “AAA” batteries	2 “AAA” batteries	Same
Operating Conditions	•+5℃ to +40℃ •10% to 90% RH , non-condensing •70 kPa to 106 kPa	• +10℃ ~ +40℃ •15% ~ 90% RH (non-condensing) • 80 kPa ~ 106 kPa	Note No.6
Storage Conditions	•-25℃ to +60℃ •10% to 90% RH, non-condensing •50 kPa to 106 kPa	• -20℃ ~ +60℃ •10% ~ 90% RH (non-condensing)	Note No.7
Dimensions (mm)	Approx. 85mm x 58mm x 21mm	91 mm x 63 mm x 13 mm (not including the wrist cuff)	Note No.8
Weight (g)	About 93g (Without batteries)	Approximately 91 g (not including batteries)	Note No.9
Operation Mode	Continuous operation	Continuous operation	Same
IP Classification	IP22	IP22	Same
Electric Classification	Internally powered, type BF applied part (cuff is applied part)	Internally powered ME equipment, Type BF (wrist cuff)	Same
Service Life	5 years	5 years	Same
Functions			
Time and Date	Yes	Yes	Same

Elements of Comparison	Subject Device	Predicate Device	Comparison
Setting			
Voice Broadcast	Optional	No	Note No.10
Voice Volume Setting	Optional	No	Note No.11
Voice On/Off Key	Optional	No	Note No.12
Unit Setting	YES Note: Display measurement results by “mmHg” or “kPa”.	No Note: Display measurement results by “mmHg” only.	Note No.13
Movement Error Indication	Yes	Yes	Same
Cuff Wrapping Detection	Yes	Yes	Same
Indications for Irregular Heartbeats	Yes	Yes	Same
Memory Function	Yes	Yes	Same
Memory Capacity	Up to 299 sets of data	Up to 100 sets of data per user	Note No.14
Bluetooth Transmission	Optional	Yes	Note No.15
Indication for Low Battery	Yes	Yes	Same
Automatic Shutdown	Yes	Yes	Same
View Average Value	View average value of latest three times measurement	• Viewing the average of the latest 2 or 3 readings taken within the most recent 10 minutes timeframe • View the weekly average readings taken in the morning over the past 4 weeks	Note No.16

Elements of Comparison	Subject Device	Predicate Device	Comparison
Blood Pressure Classification	The feature displays a user's blood pressure classification. "■" corresponds to the BP classification in 2025 AHA/ACC Hypertension Guideline.	Symbol(High): appears if the systolic blood pressure is 130 mmHg or above and/or if the diastolic blood pressure is 80 mmHg or above. Refer to classification of BP (ACC/AHA 2017 Hypertension guidelines)	Note No.17
Safety and Performance			
Performance	Comply ANSI/AAMI/ISO 81060-2 and IEC 80601-2-30	Comply ANSI/AAMI/ISO 81060-2 and IEC 80601-2-30	Same
Electrical Safety	Comply IEC 60601-1, IEC 60601-1-6 and IEC 60601-1-11	Comply IEC 60601-1, IEC 60601-1-6 and IEC 60601-1-11	Same
EMC	Comply IEC 60601-1-2	Comply IEC 60601-1-2	Same
Biocompatibility	Comply to ISO 10993 and FDA Guidance (Tested items including Cytotoxicity, Sensitization and Intracutaneous Reactivity)	Comply to ISO 10993 and FDA Guidance (Tested items including Cytotoxicity, Sensitization and Intracutaneous Reactivity)	Same
FCC	Comply with Part 15 of federal communications commission (FCC) rules	Comply with Part 15 of federal communications commission (FCC) rules	Same

Justification for the Differences

Note No.1, Note No.2, Note 3 and Note No.5:

1) According to clause 5.1.3 of ISO 81060-2:2018+AMD1:2020, the clinical investigation requirements for adults and adolescents over age 12 are essentially the same. Object evidence supports that the subject device has met the requirements in ISO 81060-2:2018+AMD1:2020 as that of the predicate device. Therefore, the subject and the predicate devices are substantially equivalent as both have met the requirements in ISO 81060-2:2018+AMD1:2020.

2) While the subject device is designed for household and medical center use and the predicate device is for home use, the difference does not affect the substantial equivalence of the devices

because healthcare professionals at the medical center are trained in medical care and they are better educated to properly use the device compared to a lay person. Thus, the addition of medical center use does not introduce new risks and does not compromise the effectiveness of the subject device relative to the predicate device.

3) The intended wrist circumference of the subject device is longer than that of the predicate device; however, the subject device's wrist circumference complies with ISO 81060-2:2018+AMD1:2020, so the subject and the predicate devices are substantially equivalent despite of their difference in the intended patient population with different wrist circumference.

4) The subject device can detect irregular heartbeats during measurements and gives signal quality indicator to alert users to potentially inaccurate blood pressure measurements. Therefore, the subject and the predicate devices are substantially equivalent in this regard.

Note No.4:
1) The subject device's cuff pressure range is 0 to 300 mmHg, whereas that of the predictive device is 0 to 299 mmHg. The slight difference does not present additional risks.

2) The subject device's pulse rate range is wider than that of the predicate device, but both contain the pulse range of the majority of the population. Therefore, the differences do not lead to additional risks.

3) The subject device's diastolic pressure range is marginally narrower than that of the predicate device, whereas the systolic pressure range is identical for both. The blood pressure measurement range of subject device complies with IEC 80601-2-30. Therefore, the differences do not lead to additional risks.

Note No.6 and Note No.7:
The operating conditions and storage conditions of the subject device and the predicate device differ slightly. While the subject devices operating and storage environment is slightly broader than that of the predicate device, the subject device's operating and storage environment meets the requirements of IEC 60601-1, IEC 60601-1-11 and IEC 80601-2-30. So, the differences do not raise any concerns regarding substantial equivalence.

Note No.8 and Note No.9:
The dimensions and weight of the subject and the predicate devices are quite similar. These parameters do not affect the substantial equivalence of the subject device. Thus, the subject device is substantially equivalent to the predicate device despite their differences in these parameters.

Note No.10, Note No.11 and Note No.12:
The subject device provides an optional voice broadcast function, whereas the predicate device does not. As this function is independent of the blood pressure algorithm, it does not present

additional risks and does not affect the substantial equivalence of the subject device to the predicate device. Thus, the subject device is substantially equivalent to the predicate device despite of this additional function.

Note No.13:
The subject device can display measurement results by "mmHg" or "kPa", while the predicate device can display by "mmHg" only. The additional display unit does not affect the substantial equivalence of the subject device. In addition, this feature is validated according to IEC 80601-2-30, so the subject device is as safe and effective as the predicate device despite of this additional feature.

Note No.14:
The predicate device's memory values are divided into User 1 and User 2, with each user able to store up to 100 sets, whereas the subject device does not distinguish between users and stores up to 299 sets. Although the memory capacity of the subject device differs slightly from that of the predicate device, this feature is for user convenience, and not the intended use of the device. In addition, both devices' memory capacity is sufficient for users to view recent measurements, thus the difference in memory capacity between the subject device and the predicate device does not raise any concerns regarding substantial equivalence.

Note No.15:
The predicate device has a Bluetooth feature whereas the subject device offers that as an option. Thus, the difference is some of the subject devices may not have the Bluetooth feature, which enables users to view measurements remotely on a mobile APP. Thus, the Bluetooth function is a nice-to-have feature and not an absolute necessity for the device to perform its intended use. This difference between the subject and the predicate device does not raise concerns regarding substantial equivalence.

Note No.16:
The predicate device offers more average readings options than the subject device. This is a nice-to-have feature and does not affect the substantial equivalence of the intended use of these devices.

Note No.17:
The subject device displays a user's BP classification per 2025 AHA/ACC Hypertension Guideline. In comparison, the predicate device does not provide BP classification, but alerts a user when systolic blood pressure is/exceeds 130 mmHg and/or diastolic blood pressure is/exceeds 80 mmHg (high BP per 2017 AHA/ACC Hypertension Guideline). Blood pressure classifications are the same for 2017 and 2025 AHA/ACC Hypertension Guidelines. As clearly stated in the User's Manual, the BP classification displayed on this device is not for clinical diagnosis, and the alert is for the patient to repeat testing and/or seek doctor's attention. Thus,

this difference between the subject and predicate devices does not raise new concerns regarding substantial equivalence.

Summary of Testing

1) Nonclinical Testing Summary

The design and manufacturing of YUWELL® Electronic Blood Pressure Monitor are subject to verification and validation testing in conformance with regulatory guidance and recognized consensus standards.

- Electrical safety test according to ANSI/AAMI/IEC 60601-1, IEC 60601-1-8, IEC 60601-1-11 and IEC 80601-2-30 standards
- Electromagnetic compatibility test according to IEC 60601-1-2 and IEC TS 60601-4-2 standards
- Usability test according to IEC 60601-1-6 and IEC 62366-1 standards
- Performance test according to IEC 80601-2-30 standard
- The irregular heartbeat (IHB) feature of the subject device serves as a signal quality indicator to alert users to potentially inaccurate blood pressure measurements. This feature has been validated through testing using a blood pressure simulator. To set up the test, the blood pressure simulator was set to the arrhythmia mode. The arrhythmia mode mentioned herein refers solely to the preset mechanical simulation waveforms of the blood pressure simulator, which are used to test the IHB signal quality indication function. First, the simulator's output waveforms were verified to meet the definition of an irregular pulse wave and the preset values were recorded. Second, the subject device's readings were compared against the simulator's preset values. Third, ten sets of measurements were compiled in each mode, and the mean absolute deviation between the subject device readings and the simulator's preset values was calculated. The mean absolute deviation for both systolic and diastolic pressures exceeded 5 mmHg, it demonstrated that the blood pressure measurement was inaccurate when the IHB symbol was present.
- Biocompatibility test according to ISO 10993 and the FDA guidance "Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"
- Software verification and validation per FDA guidance "Content of Premarket Submissions for Device Software Functions" and "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" and IEC 62304
- Bluetooth transmission complies with Part 15 of federal communications commission (FCC) rules

2) Clinical Testing summary

i) Blood Pressure Clinical Testing

The accuracy of YUWELL® Electronic Blood Pressure Monitor has been demonstrated through a clinical study per ISO 81060-2:2018+AMD1:2020 in the intended patient population, which is individuals over 12 years old. The study included Eighty-five (85) subjects, who met the study inclusion criteria for wrist circumference and systolic and diastolic BP. Validation and data analysis were performed per protocol. In the ISO 81060-2:2018+AMD1:2020 validation procedure (criterion 1), the mean ± SD of the differences between the test device and the reference BP was 1.1 ± 6.7/0.4 ± 7.2 mmHg (systolic/diastolic). The mean differences between the two observers and the test device readings were 1.1 ± 5.8 mmHg for systolic BP and 0.4 ± 6.6 mmHg for diastolic BP (criterion 2). The clinical study results have met both ISO criteria, and thus validated the accuracy of YUWELL® Electronic Blood Pressure Monitor.

ii) Pulse Rate Clinical Testing

A clinical validation study was conducted to evaluate the pulse rate (PR) measurement accuracy of the subject device by comparison with manually annotated electrocardiogram (ECG) recordings. The study had a total of thirty-five (35) subjects enrolled, and all their age were above 12 years old. Their validated pulse rate ranged from 42 to 183 bpm with no subjects excluded from the analysis. The study method is as such: Following a 5-minute seated rest, the subject's pulse rate was measured simultaneously by the subject device and a reference ECG. There were three (3) repeated measurements per subject, yielding 35x3=105 data sets that resulted in a mean error of -0.38 bpm, a standard deviation of 1.76 bpm, and an overall root mean square error of 1.79 bpm. Bland-Altman analysis revealed all the observed differences were within the pre-defined acceptance criterion of ±5%. These results demonstrated good agreement between the device PR outputs and the ECG reference values across the validated range.

Conclusion

Compared to the predicate device, the subject device has similar intended use and technical characteristics as the predicate device. All testing results have demonstrated that the subject device is as safe and effective as the predicate device. Therefore, they are substantially equivalent.