December 15, 2023

Masimo Corporation
Sindura Penubarthi
Associate Director, Regulatory Affairs
52 Discovery
Irvine, California 92618

Re: K223721
Trade/Device Name: Masimo Stork
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA, FLL
Dated: October 2, 2023
Received: October 4, 2023

Dear Sindura Penubarthi:

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.

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,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
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Device Name

Masimo Stork

Indications for Use *(Describe)*

The Masimo Stork is a wearable device intended for the monitoring of multiple physiological parameters. Masimo Stork is intended to be used in home environments.

The Masimo Stork is indicated for the spot-checking and continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and Pulse Rate (PR) in infants and neonates during no-motion, motion, and low perfusion conditions.

The Masimo Stork is also indicated for continuous skin temperature measurements of infants and neonates.

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.

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Irvine, CA 92618

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Submitter and Address of Manufacturing Facility:	Masimo Corporation 52 Discovery Irvine, CA 92618 Phone: (949) 297-7000 FAX: (949) 297-7592
Date:	December 15, 2023
Contact:	Sindura Penubarthi Associate Director, Regulatory Affairs Masimo Corporation Phone: (949) 396-4041
Trade Name:	Masimo Stork
Common Name:	Oximeter
Classification Regulation/ Product Code:	21 CFR 870.2700, Class II/DQA
Additional Product Code:	FLL
Establishment Registration Number:	3011353843
Reason for Premarket Notification:	New Device
Predicate Device:	K203208 – Guardian Angel Rx GA2000 Series Digital Vital Signs Monitoring System
Reference Device:	K191059 – Masimo Rad-97 and Accessories including RD SET Adhesive sensors

1. Device Description

The Masimo Stork is a wearable device that is applied to a baby's foot for the spot-checking and continuous monitoring of functional arterial oxygen saturation (SpO2), pulse rate (PR), and skin temperature. Masimo Stork is provided with wireless communication capabilities (e.g., Bluetooth) so that the parameter data can be communicated for monitoring (e.g., display, alarms).

The Stork combines the signal processing and optical components (i.e., signal detecting parts) into a single pulse oximetry module. The module is flat to allow for the flush contact with a baby (e.g., neonate, infant) foot.

Masimo Stork can be used with following components:

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1. Stork Boot ("Boot") is a silicone holder that helps in the placement and securement of the Stork on to the baby's foot.

2. Stork Hub ("Hub") is an alarm/ connectivity device that helps in the communication of the physiological data wirelessly from Stork to a software application. The Hub provides the charging of the Stork and can optionally be provided with a camera.

3. Stork App ("App") is mobile device application that is connected through the Hub and/or directly to the Stork to provide the user interface for viewing and monitoring the physiological parameters.

4. Stork Cloud ("Cloud") is the software that helps to store the physiological data. It also helps to monitor the wireless connections between the Hub, App, and Stork.

The Masimo Stork specifications are as follows:

Masimo Stork	
Feature	**Specifications**
Remote Access to Monitored Data	Yes
Support Communication Types	Wireless
Wireless Protocols Supported	Bluetooth, Wi-Fi
Communication Security	Encryption
Continuous Display of Parameter Data	Yes
Supported Display Devices	Smart Device
User Interface	Touchscreen (Smart Device)
Performance Specifications	
SpO2, No Motion (70-100%)	1.5%
SpO2, Motion (70-100%)	1.5%
SpO2, Low Perfusion (70-100%)	2%
Pulse Rate, No Motion (25-240 bpm)	3 bpm
Pulse Rate, Motion (25-240 bpm)	5 bpm
Pulse Rate, Low Perfusion (25-240 bpm)	3 bpm
Temperature [25°C to 43°C (77°F to 109.4°F)]	±0.3°C (±0.54°F)
Electrical Specifications	
Battery Type	Internal Rechargeable Lithium ion
Environmental Specifications	
Operating Temperature	32°F to 104°F (0°C to 40°C)
Operating Humidity	10% to 95%, non-condensing
Storage/Transport Temperature	-4°F to 140°F (-20°C to 60°C)
Storage/Transport Humidity	10% to 95%, non-condensing
Classification per IEC 60601-1	
Electrical Safety	IEC 60601-1
EMC	IEC 60601-1-2
Electrical Isolation Type	Class II (Internally Powered)
Applied Part Type	BF Applied Part
Ingress Protection	IP22
Mode of Operation	Continuous

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Masimo Hub	
Feature	**Specifications**
Electrical Specifications	
Types of Power Source	AC
AC Electrical Power Rating	100 to 240 VAC, 50 to 60 Hz, 0.2A
Environmental Specifications	
Operating Temperature	41°F to 95°F (5°C to 35°C)
Operating Humidity	10% to 95%, non-condensing
Storage/Transport Temperature	-4°F to 140°F (-20°C to 60°C)
Storage/Transport Humidity	10% to 95%, non-condensing

2. Intended Use/ Indications for Use

The Masimo Stork is a wearable device intended for the monitoring of multiple physiological parameters. Masimo Stork is intended to be used in home environments.

The Masimo Stork is indicated for the spot-checking and continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and Pulse Rate (PR) in infants and neonates during no-motion, motion, and low perfusion conditions.

The Masimo Stork is also indicated for continuous skin temperature measurements of infants and neonates.

3. Technological Characteristics

Principle of Operations

The subject device, Masimo Stork, utilizes the same principles of operation as other FDA cleared Masimo SET pulse oximetry devices. Masimo SET pulse oximetry relies on the Beer-Lambert law and the following principles of pulse oximetry to provide estimates of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate:

- Oxyhemoglobin (oxygenated blood) and deoxyhemoglobin (non-oxygenated blood) differ in their absorption of red and infrared light (spectrophotometry).

- The amount of arterial blood in tissue changes with your pulse (photoplethysmography). Therefore, the amount of light absorbed by the varying quantities of arterial blood changes as well.

These principles of operation are combined with the use of advanced signal processing algorithms as part of the FDA cleared Masimo SET pulse oximetry technology to help to minimize the impact of confounding factors, such as static absorbers (e.g., skin pigmentation, site thickness differences). The advanced signal processing features allow for better detection of the arterial signal.

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The Masimo Stork also provides a skin temperature monitoring feature that relies on the principle of operations of a thermistor.

Mechanism of Action for Achieving the Intended Effect

The Masimo Stork achieves its intended effect by the application on to the baby's foot. To keep the Stork in place, a bootie shaped holder is provided that secures the sensors in place. The Stork provides wireless capabilities so that a cabled connection is not required to transmit the parameters measurements continuously. The wireless communication is established by a paired Bluetooth connection to support alarms and display. To support the display of the parameter data monitored by the Stork, a smart device software application is used as a user interface. The software application displays the parameter data and provides notifications of alarm conditions. The software application (App) also allows for the viewing of parameter trend information. The Hub that is used with the Stork is provided with an integrated speaker and visual indicators to also notify of alarm conditions independent of the App. The Hub provides redundancy in the event the smart device battery is depleted or the alarm notifications on the App are not detected.

4. Summary of Technological Characteristics of Subject Device Compared to Predicate Device

Similarities and Differences between Predicate and Subject Device

The subject device, Masimo Stork, and the predicate device, Guardian Angel (K203208), have the following key similarities:

- Both devices have the same intended use;
- Both devices are wearable;
- Both devices support similar monitoring technologies (SpO2, PR, and Temperature);
- Both devices utilize wireless capabilities to allow for data to be transmitted for remote display and monitoring using a software application;
- Both devices provide audible and visual alarms.

The subject device, Masimo Stork, and the predicate device, Guardian Angel (K203208), have the following key differences:

- The subject device monitors skin temperature on the baby's foot.

As part of the submission, data was provided to support both devices have the same intended use. Testing was also provided to support the substantial equivalence of the subject device.

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Comparison between Subject and Predicate Device			
Feature	**Masimo Stork Subject Device**	**Guardian Angel Rx GA2101 Digital Vital Signs Monitoring System Predicate Device (K203208)**	**Comparison to Predicate Device**
Classification	Class II, Oximeter	Class II, Oximeter	Same.
Regulation, Product Code	21 CFR 870.2700, Class II/DQA	21 CFR 870.2700, Class II/DQA	Same.
Additional Product Code(s)	FLL	FLL	Same.
Intended Use	The Masimo Stork is a wearable device intended for the monitoring of multiple physiological parameters. Masimo Stork is intended to be used in home environments. The Masimo Stork is indicated for the spot-checking and continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and Pulse Rate (PR) in infants and neonates during no-motion, motion, and low perfusion conditions. The Masimo Stork is also indicated for continuous skin temperature measurements of infants and neonates.	The Guardian Angel Rx GA2000 Series Digital Vital Sign Monitoring System (Model GA2101) is indicated for use in measuring, recording, and displaying functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) and body temperature. The intended environments of use are hospitals medical facilities, home care, and subacute environments. This system is a reusable device. The Oximeter Module(s) is indicated for spot checking and/or continuous monitoring of SpO2 and PR of pediatrics and infants during non-motion and under well perfused conditions. The Thermometer Module is indicated for continuous armpit body temperature monitoring of pediatrics, and infants.	Same.
Principles of Operation	The pulse oximeter technology relies on the absorption differences of red and infrared light to determine SpO2 and Pulse Rate.	The pulse oximeter technology relies on the absorption differences of red and infrared light to determine SpO2 and Pulse Rate.	Same.

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Comparison between Subject and Predicate Device			
Feature	**Masimo Stork Subject Device**	**Guardian Angel Rx GA2101 Digital Vital Signs Monitoring System Predicate Device (K203208)**	**Comparison to Predicate Device**
	Temperature measure relies on a thermistor that correlates temperature to impedance changes.	Temperature measure relies on a thermistor that correlates temperature to impedance changes.	
Parameters Monitored	SpO2, PR, Temperature	SpO2, PR, Temperature	Same.
Supported Display Devices	Smart Device App	Display Unit, Smart Device App	Similar. Both devices display measurements on a smart device app. The predicate device also supports the ability to display measurements to a separate display unit. Testing is provided to support the display unit is not needed.
Pulse Oximeter Sensor Type	Reusable	Reusable with Disposable Adhesives	Different. Subject device does not use a disposable adhesive to secure the sensor. Testing is provided to support the difference does not raise different questions of safety and effectiveness.
Temperature Sensor Type	Reusable	Disposable	Different. Subject device is reusable. Testing is provided to support the difference does not raise different

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Comparison between Subject and Predicate Device			
Feature	**Masimo Stork Subject Device**	**Guardian Angel Rx GA2101 Digital Vital Signs Monitoring System Predicate Device (K203208)**	**Comparison to Predicate Device**
			questions of safety and effectiveness.
Indicated population	Infants, Neonates (<18 months)	Infants	Similar. Subject device covers wider patient category aligned with reference device. Testing is provided to support the performance on the wider population.
Remote Access to Monitored Data	Yes	Yes	Same.
Supported Alarms	SpO2, PR, and Temperature	SpO2, PR and Temperature	Same.
Type of Alarm	Audible and visual	Audible and visual	Same.
Distributed Alarm System	Yes	Yes	Same.
Supported Communication	Bluetooth, Wi-Fi	Bluetooth, Wi-Fi	Same.
Communication Security	Encryption	Unknown	Subject device provides encrypted communication.
Pulse Oximetry Sensor Application Site	Foot	Foot	Same.

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Comparison between Subject and Predicate Device			
Feature	**Masimo Stork Subject Device**	**Guardian Angel Rx GA2101 Digital Vital Signs Monitoring System Predicate Device (K203208)**	**Comparison to Predicate Device**
Performance Specifications			
SpO2, No Motion (70-100%)	1.5%	3%	Different. Subject device includes improved performance specification similar to reference device RD SET Adhesive Sensor (K191059).
SpO2, Motion (70-100%)	1.5%	No motion only	Different. Subject device includes improved performance specification similar to reference device RD SET Adhesive Sensor (K191059).
SpO2, Low Perfusion (70-100%)	2%	Well perfused only	Different. Subject device includes improved performance specification similar to reference device RD SET Adhesive Sensor (K191059).
Pulse Rate, No Motion	Range: 25-240 bpm, 3 bpm Arms	Range: 30-290 bpm, 3 bpm Arms	Different. Subject device supports a different specification range. Testing provided to support the performance across the specification range.
Pulse Rate, Motion	Range: 25-240 bpm, 3 bpm Arms	No motion only	Different. Subject device supports a different specification range. Testing provided to support the performance across the specification range.
Pulse Rate, Low Perfusion	Range: 25-240 bpm, 3 bpm Arms	Well perfused only	Different. Subject device supports a different specification range.

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Comparison between Subject and Predicate Device			
Feature	**Masimo Stork Subject Device**	**Guardian Angel Rx GA2101 Digital Vital Signs Monitoring System Predicate Device (K203208)**	**Comparison to Predicate Device**
			Testing provided to support the performance across the specification range.
Temperature, Measurement Accuracy	+/- 0.3°F	+/- 0.2°F	Different. The subject device has a different claimed accuracy. Testing is provided to support the performance specification
Temperature Measurement Site	Foot	Axillary	Different. Subject device has different application site. Testing is provided to support the performance specification.
Enclosure Material	Thermoplastic	Thermoplastic	Same.
Overall Dimension	2.48” x 1.90” x 1.17”	Unknown	Different. Subject device has a different form factor form the predicate. Testing is provided to support there is no significant differences.
Operating Temperature	5°C to 35°C (41°F to 95°F)	5°C to 40°C (41°F to 104°F)	Different. Subject device has different claimed operating range. Testing is provided to support the specified range.

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Comparison between Subject and Predicate Device			
Feature	**Masimo Stork Subject Device**	**Guardian Angel Rx GA2101 Digital Vital Signs Monitoring System Predicate Device (K203208)**	**Comparison to Predicate Device**
Operating Humidity	10% to 95%, non-condensing	15% to 95%, non-condensing	Different. Subject device has different claimed operating range. Testing is provided to support the specified range.
Storage/ Transport Temperature	-20°C to 60°C (-4°F to 140°F)	-25°C to 70°C (-13°F to 158°F)	Different. Subject device has different claimed storage and transport range. Testing is provided to support the specified range.
Storage/ Transport Humidity	10% to 95%, non-condensing	10% to 93%, non-condensing	Different. Subject device has different claimed storage and transport range. Testing is provided to support the specified range.
Electrical Safety	IEC 60601-1	IEC 60601-1	Same.
EMC	IEC 60601-1-2	IEC 60601-1-2	Same.
Applied Part Type	BF Applied Part	BF Applied Part	Same.
Ingress Protection	IP22	Unknown	Subject device provides testing to support the claimed ingress protection rating.
Mode of Operation	Continuous	Continuous	Same.

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5. Performance Data

To support the substantial equivalence, performance clinical and bench testing was conducted and is included as part of this submission.

Performance Bench Testing

Bench testing was performed on the Masimo Stork to support the device met its applicable safety and performance specifications. The non-clinical testing was conducted in accordance with Masimo requirements to ensure that the specifications of the subject device were met. The following non-clinical testing was performed:

- Biocompatibility testing per ISO 10993-1
- Electrical safety testing per IEC 60601-1
- EMC testing per IEC 60601-1-2
- Usability testing per FDA Human Factors and Usability Guidance
- Software verification and validation testing per FDA Software Guidance
- Mechanical testing per IEC 60601-1
- Performance testing per ISO 80601-2-61

Laboratory Accuracy Testing

To support the temperature measurement feature of the Stork, performance bench testing was conducted in accordance with ISO 80601-2-56 that compared the accuracy of the surface temperature measurements against a reference temperature source to establish the laboratory accuracy.

Biocompatibility Testing

The patient contacting materials of Masimo Stork and Boot were tested to be biocompatible in accordance with ISO 10993.

Electromagnetic Compatibility, Electrical Safety, Environmental, Mechanical and Cleaning

Electromagnetic compatibility testing was conducted in accordance with IEC 60601-1-2 and electrical safety in accordance with IEC 60601-1 standard. The environmental, mechanical, and chemical resistance testing has also been provided to support the safety of Masimo Stork.

Wireless Testing

As the Stork relies on the use of wireless technologies in the display and alarming capabilities, the design of the Stork includes mitigations for potential disruptions in communication. The wireless information was provided in accordance with FDA's *Guidance for Industry and FDA Staff-Radio*

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Frequency Wireless Technology in Medical Devices, dated August 2013.

Software Testing

The Stork relies on the software to achieve its intended purpose, as a result a process consistent with IEC 62304 is followed in the development of the software. The software for this device is classified as a moderate level of concern consistent with the FDA Guidance for Pulse Oximeters.

Software verification and validation testing was conducted and documented in accordance with FDA's Guidance, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, dated May 11, 2005. The software for this device was considered as a "moderate" level of concern because a failure or latent flaw in the software could directly result in minor to moderate injury to the patient.

Cybersecurity Testing

As the Masimo Stork relies on external communication and software to provide its intended purpose, the design accounts of the mitigations against cybersecurity risks. The cybersecurity information was provided in accordance with FDA *Guidance for Industry and Food and Drug Administration Staff-Content of Premarket Submissions for Management of Cybersecurity in Medical Devices,* dated October 2, 2014.

Human Factors Usability Testing

To support the design features that are unique to the Stork, human factors testing is conducted in accordance with the FDA Guidance, *Applying Human Factors and Usability Engineering to Medical Devices, February 3, 2016.*

Clinical Testing

To support the performance of the Masimo Stork, three clinical studies are provided as part of this submission. A study was conducted to support the equivalence of the performance of the Masimo Stork to the FDA clearance RD SET Adhesive sensor (K191059). This testing included data from 30 subjects of light (14) and dark (16) skin pigmented subjects undergoing a desaturation protocol in accordance with ISO 80601-2-61.

To support the form, fit, and function of the Masimo Stork for its indicated population, two clinical studies were conducted. One study was conducted on 41 infants and neonates across different skin pigmentations (22 dark, 20 light), ages (21 male, 21 female), weights, and genders comparing the Masimo Stork SpO2 values to an FDA cleared pulse oximeter.

The other study was an overnight study that was performed on 19 infants and neonates in which parents used the Masimo Stork overnight on their babies in a home environment. The study was done to support the safe prolonged use. The data also supported the acceptability of Masimo Stork in

preventing non-actionable alarms and the good availability of the continuous monitoring throughout the use (99.7% under low motion conditions).

The performance testing was found to support the subject device does not raise different questions of safety and effectiveness from that of the predicate device.

6. Conclusion

The submission supported the Masimo Stork is substantially equivalent to the predicate device.