May 3, 2024

Masimo Corporation
Kertana Shankar
Regulatory Manager
52 Discovery
Irvine, California 92618

Re: K234021
Trade/Device Name: Masimo Stork
Regulation Number: 21 CFR 870.2705
Regulation Name: Infant pulse rate and oxygen saturation monitor for over-the-counter use
Regulatory Class: Class II
Product Code: QYU, FLL
Dated: December 19, 2023
Received: December 20, 2023

Dear Kertana Shankar:

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,

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

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)*
K234021

Device Name
Masimo Stork

Indications for Use *(Describe)*

The Masimo Stork is a wearable device intended for the monitoring of multiple physiological parameters.

The Masimo Stork is indicated for the spot-checking and continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and Pulse Rate (PR) during no-motion, motion, and low perfusion conditions of infants and neonates who are 0 to 18 months of age and between 6 to 30 lbs. The Masimo Stork™ is also indicated for continuous skin temperature measurements of infants and neonates who are 0 to 18 months and between 6 to 30 lbs. Masimo Stork™ is indicated for use in home environments.

The Masimo Stork can be used to supplement a caregiver's decision to seek additional guidance for the care of an infant or neonate. It is not intended to provide notifications for every episode of the unexpected occurrences of elevated or depressed PR or a low SpO2; rather, the Masimo Stork™ is intended to provide a notification only when sufficient data are available for analysis.

The Masimo Stork is not intended to replace the monitoring, diagnosis, or treatment provided by a physician or healthcare provider. The Masimo Stork is not intended for use with infants and neonates previously diagnosed with cardiovascular or respiratory disease or conditions.

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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Submitter and Address of Manufacturing Facility:	Masimo Corporation 52 Discovery Irvine, CA 92618 Phone: (949) 297-7000 FAX: (949) 297-7592
Date:	April 26, 2024
Contact:	Kertana Shankar Regulatory Manager Masimo Corporation Phone: (949) 390-0140
Trade Name:	Masimo Stork
Common Name:	Infant pulse rate and oxygen saturation monitor for over-the-counter use
Classification Regulation/ Product Code:	21 CFR 870.2705, Class II/ QYU
Additional Product Code:	FLL
Establishment Registration Number:	3011353843
Reason for Premarket Notification:	Introduction of Masimo Stork for OTC use
Predicate Device:	DEN220091 – Dream Sock
Reference Device:	K223721 – Masimo Stork

1 Device Description

This submission covers the introduction of the Masimo Stork for OTC use. The subject device was previously cleared with different indications under K223721 for prescription use. 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 Masimo Stork can be used with the following components:

- Stork Boot: The Stork Boot is a silicone holder that helps in the placement and securement of the Stork on to the baby's foot.

- Stork Hub: The Stork Hub is an alarm and connectivity device that helps in the communication of 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.

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- Stork App: The Stork App is a mobile device application installed on a smart device that provides the graphical user interface for the Stork for viewing and monitoring the physiological parameters.

- Stork Cloud: The Stork Cloud is software that helps to store physiological data.

The Masimo Stork specifications are provided in Tables 1-1 and 1-2:

Table 1-1: Masimo Stork Specifications	
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
Battery Life	16 hours
Mechanical Specifications	
Overall Dimension	2.48” x 1.90” x 1.17”
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
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

Table 1-2: Masimo Hub Specifications	
Feature	**Specifications**
Electrical Specifications	
Types of Power Source	AC
AC Electrical Power Rating	100 to 240 VAC, 50 to 60 Hz, 0.2A

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Table 1-2: Masimo Hub Specifications	
Feature	**Specifications**
Mechanical Specifications	
Overall Dimension	2.39” x 2.39” x 2.0” (6.07 x 6.07 x 5.08 cm)
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.

The Masimo Stork is indicated for the spot-checking and continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and Pulse Rate (PR) during no-motion, motion, and low perfusion conditions of infants and neonates who are 0 to 18 months of age and between 6 to 30 lbs. The Masimo Stork is also indicated for continuous skin temperature measurements of infants and neonates who are 0 to 18 months and between 6 to 30 lbs. Masimo Stork is indicated for use in home environments.

The Masimo Stork can be used to supplement a caregiver's decision to seek additional guidance for the care of an infant or neonate. It is not intended to provide notifications for every episode of the unexpected occurrences of elevated or depressed PR or a low SpO2; rather, the Masimo Stork is intended to provide a notification only when sufficient data are available for analysis.

The Masimo Stork is not intended to replace the monitoring, diagnosis, or treatment provided by a physician or healthcare provider. The Masimo Stork is not intended for use with infants and neonates previously diagnosed with cardiovascular or respiratory disease or conditions.

3 Technological Characteristics

Principle of Operation

There were no changes made to the principles of operation of the subject device, Masimo Stork, as part of this submission from the previous clearance under K223721.

The subject device still relies on Masimo SET pulse oximetry, which 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.

The Masimo Stork also provides a skin temperature monitoring feature that relies on the principle of operations of a thermistor, which relies on the correlation of the detected junction temperature to difference in impedances. These impedances are then processed to calculate the temperature at the measurement site.

Mechanism of Action for Achieving the Intended Effect

There were no changes made to the mechanism of action of the subject device, Masimo Stork, as part of this submission from the previous clearance under K223721.

The Masimo Stork still 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 sensor in place. The Stork provides wireless capabilities so that a cabled connection is not required for the continuous transmission of the parameter measurements. The wireless communication is established using Bluetooth 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 the 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 provided 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 Discussion of Similarities and Differences Between the Predicate and Subject Device

Similarities and Differences between the Predicate and Subject Device

The subject device, Masimo Stork, and the predicate device, Owlet Dream Sock (DEN220091), have the following key similarities:

- Both devices have the same intended use.
- Both devices are wearable.
- Both devices support monitoring of SpO2 and PR.
- Both devices support wireless communication for the transfer of physiological data for remote display and monitoring.

The subject device, Masimo Stork, and the predicate device, Owlet Dream Sock (DEN220091), have the following key differences:

- The subject device is indicated for a wider patient population.
- The subject device additionally monitors skin temperature.

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The purpose of this submission is the introduction of Masimo Stork for over-the-counter use. The subject device was previously cleared with different indications under K223721 for prescription use. To support the substantial equivalence of the subject device, the Dream Sock (DEN220091) is included as the predicate device. Between the subject and the predicate device, Dream Sock (DEN220091), there are no differences in the intended use of pulse oximetry monitoring. Both the subject device and predicate device have similar technological characteristics, but the subject device provides a different SpO2 performance specification of 1.5% Arms versus the predicate device that reports a 3% Arms specification.

To support the improvement in the SpO2 performance does not raise different questions of safety and effectiveness, the previous clearance for the Masimo Stork, K223721, is included as the reference device. The performance of the Masimo Stork parameters has not changed from its previous clearance under K223721.

Refer to Table 4-1 below for the detailed comparison between the subject and predicate devices.

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Table 4-1 Comparison between Subject and Predicate Devices			
Feature	**Masimo Stork Subject Device (K234021)**	**Dream Sock Predicate Device (DEN220091)**	**Comparison to Predicate**
Classification	Class II, Infant pulse rate and oxygen saturation monitor for over-the-counter use	Class II, Infant pulse rate and oxygen saturation monitor for over-the-counter use	Same as the predicate device.
Regulation, Product Code	21 CFR 870.2705, Class II/ QYU	21 CFR 870.2705, Class II/ QYU	Same as the predicate device.
Additional Product Code(s)	FLL	N/A	Different from the predicate device. The subject device additionally supports skin temperature feature, same as the feature cleared as part of K223721.
Indications for Use	The Masimo Stork is a wearable device intended for the monitoring of multiple physiological parameters. The Masimo Stork is indicated for the spot-checking and continuous monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and Pulse Rate (PR) during no-motion, motion, and low perfusion conditions of infants and neonates who are 0 to 18 months of age and between 6 to 30 lbs. The Masimo Stork is also indicated for continuous skin temperature measurements of infants and neonates who are 0 to 18 months and between 6 to 30 lbs. Masimo Stork is indicated for use in home environments. The Masimo Stork can be used to supplement a caregiver's decision to seek additional guidance for	The Dream Sock analyzes photoplethysmography data to identify instances when the infant's pulse rate (PR) and/or oxygen saturation (SpO2) moves outside a preset range, and provides a notification to the caregiver, prompting them to assess the infant. The Dream Sock also displays the infant's PR and SpO2 values to the caregiver and displays trends in these measured values, and their relationship to the preset ranges, over time. These PR and SpO2 notifications and displays on the Dream Sock are intended for use in infants who are 1 to 18 months of age and between 6 to 30 lbs.	Same as the predicate device. Both devices are intended to monitor babies using pulse oximetry features with alarms.

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Table 4-1 Comparison between Subject and Predicate Devices			
Feature	**Masimo Stork Subject Device (K234021)**	**Dream Sock Predicate Device (DEN220091)**	**Comparison to Predicate**
	the care of an infant or neonate. It is not intended to provide notifications for every episode of the unexpected occurrences of elevated or depressed PR or a low SpO2; rather, the Masimo Stork is intended to provide a notification only when sufficient data are available for analysis. The Masimo Stork is not intended to replace the monitoring, diagnosis, or treatment provided by a physician or healthcare provider. The Masimo Stork is not intended for use with infants and neonates previously diagnosed with cardiovascular or respiratory disease or conditions.	The Dream Sock is intended for over-the-counter (OTC) use only in a home environment. It is not intended to provide notification for every episode of the unexpected occurrences of elevated or depressed PR or a low SpO2 level; rather, the Dream Sock is intended to provide a notification only when sufficient data are available for analysis. The notifications and associated data can be used to supplement the decision by caregivers to seek additional guidance for medical care of the infant. Dream Sock is not intended to replace traditional methods of monitoring, diagnosis, or treatment. The Dream Sock is not intended for use with infants previously diagnosed with cardiovascular or respiratory disease or conditions.	
Principles of Operation	The pulse oximeter technology relies on the absorption differences of red and infrared light to determine SpO2 and Pulse Rate. Temperature measure relies on a thermistor that correlates temperature to impedance changes.	The pulse oximetry sensor uses red and infrared light which is transmitted through oxyhemoglobin and are sensed in the photoelectric cell. The red and infrared light is absorbed in different amounts depending on the oxygenation of the blood.	Similar to the predicate device. The subject device additionally supports skin temperature feature, same as the feature cleared as part of K223721.
Parameters Monitored	SpO2, PR, Temperature	SpO2, PR	Similar to the predicate device.

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Table 4-1 Comparison between Subject and Predicate Devices			
Feature	**Masimo Stork Subject Device (K234021)**	**Dream Sock Predicate Device (DEN220091)**	**Comparison to Predicate**
			The subject device additionally supports skin temperature feature, same as the feature cleared as part of K223721.
Supported Display Devices	Smart Device App	Smart Device App	Same as the predicate device.
Pulse Oximeter Sensor Type	Reusable	Reusable	Same as the predicate device.
Temperature Sensor Type	Reusable	N/A	Different from the predicate device. The subject device additionally supports skin temperature feature, same as the feature cleared as part of K223721.
Indicated population	Infants, Neonates (<18 months)	Infants (1-18 months)	Similar to the predicate device. The subject device is indicated for a wider patient population, same as the feature cleared as part of K223721.
Remote Access to Monitored Data	Yes	Yes	Same as the predicate device.
Supported Alarms	SpO2, PR, and Temperature	SpO2 and PR	Similar to the predicate device. The subject device additionally supports skin temperature

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Table 4-1 Comparison between Subject and Predicate Devices			
Feature	**Masimo Stork Subject Device (K234021)**	**Dream Sock Predicate Device (DEN220091)**	**Comparison to Predicate**
			feature, same as the feature cleared under K223721.
Type of Alarm	Audible and visual	Audible and visual	Same as the predicate.
Distributed Alarm System	Yes	Yes	Same as the predicate.
Supported Communication	Bluetooth, Wi-Fi	Bluetooth	Similar to the predicate device, same as the feature cleared under K223721. Testing performed on the device supports the substantial equivalence.
Communication Security	Encryption	Unknown	Different from the predicate device, same as the feature cleared under K223721. Testing performed on the device supports the substantial equivalence.
Pulse Oximetry Sensor Application Site	Foot	Foot	Same as the predicate device.
Performance Specification			
SpO2, No Motion (70-100%)	1.5%	3%	Different from the predicate device, same as the feature cleared under K223721.

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Table 4-1 Comparison between Subject and Predicate Devices			
Feature	**Masimo Stork Subject Device (K234021)**	**Dream Sock Predicate Device (DEN220091)**	**Comparison to Predicate**
			Performance testing performed on the device supports the substantial equivalence.
SpO2, Motion (70-100%)	1.5%	Not specified	Different from the predicate device, same as the feature cleared under K223721. Performance testing performed on the device supports the substantial equivalence.
SpO2, Low Perfusion (70-100%)	2%	Not specified	Different from the predicate device, same as the feature cleared under K223721. Performance testing performed on the device supports the substantial equivalence.
Pulse Rate, No Motion	3 bpm Arms, 25-240 bpm	3 bpm Arms, 30-300 bpm	Different from the predicate device, same as the feature cleared under K223721. Performance testing performed on the device supports the substantial equivalence.
Pulse Rate, Motion	5 bpm Arms, 25-240 bpm	Not specified	Different from the predicate device, same as the feature cleared under K223721.

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Table 4-1 Comparison between Subject and Predicate Devices			
Feature	**Masimo Stork Subject Device (K234021)**	**Dream Sock Predicate Device (DEN220091)**	**Comparison to Predicate**
			Performance testing performed on the device supports the substantial equivalence.
Pulse Rate, Low Perfusion	3 bpm Arms, 25-240 bpm	Not specified	Different from the predicate device, same as the feature cleared under K223721. Performance testing performed on the device supports the substantial equivalence.
Temperature, Measurement Accuracy	+/- 0.3°C	N/A	Different from the predicate device, same as the feature cleared under K223721. Performance testing performed on the device supports the substantial equivalence.
Temperature Measurement Site	Foot	Foot	Same as the predicate device.
Enclosure Material	Thermoplastic	Unknown	Different from the predicate device, same as the feature cleared under K223721. Testing performed on the device supports the substantial equivalence.

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Table 4-1 Comparison between Subject and Predicate Devices			
Feature	**Masimo Stork Subject Device (K234021)**	**Dream Sock Predicate Device (DEN220091)**	**Comparison to Predicate**
Overall Dimension	2.48” x 1.90” x 1.17”	Unknown	Different from the predicate device, same as the feature cleared under K223721. Testing performed on the device supports the substantial equivalence.
Operating Temperature	5°C to 35°C (41°F to 95°F)	5°C to 40°C (41°F to 104°F)	Different from the predicate device, same as the feature cleared under K223721. Testing performed on the device supports the substantial equivalence.
Operating Humidity	10% to 95%, non-condensing	15% to 90%, non-condensing	Different from the predicate device, same as the feature cleared under K223721. Testing performed on the device supports the substantial equivalence.
Storage/ Transport Temperature	-20°C to 60°C (-4°F to 140°F)	-25°C to 70°C (-13°F to 158°F)	Different from the predicate device, same as the feature cleared under K223721. Testing performed on the device supports the substantial equivalence.

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Table 4-1 Comparison between Subject and Predicate Devices			
Feature	**Masimo Stork Subject Device (K234021)**	**Dream Sock Predicate Device (DEN220091)**	**Comparison to Predicate**
Storage/ Transport Humidity	10% to 95%, non-condensing	0% to 90%, non-condensing	Different from the predicate device, same as the feature cleared under K223721. Testing performed on the device supports the substantial equivalence.
Electrical Safety	IEC 60601-1	Unknown	Different from the predicate device, same as the feature cleared under K223721. Testing performed on the device supports the substantial equivalence.
EMC	IEC 60601-1-2	IEC 60601-1-2	Same as the predicate device.
Applied Part Type	BF Applied Part	Unknown	Same as the predicate device.
Ingress Protection	IP22	Unknown	Same as the predicate device.
Mode of Operation	Continuous	Continuous	Same as the predicate device.

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5 Performance Data

There were no hardware or software changes made to the subject device from the previous clearance under K223721.

Performance Bench Testing

There were no hardware or software changes made to the subject device as part of this submission; therefore, the performance testing from the previous clearance (K223721) was leveraged to support the subject device met the special controls of product code QYU and its performance specifications.

Biocompatibility Testing

There were no changes made to the patient contacting materials of the subject device from the previous clearance under K223721; therefore, the biocompatibility testing from the previous clearance was leveraged to support the subject device met the special controls of product code QYU, and its biocompatibility risk acceptability.

Electromagnetic Compatibility, Electrical Safety, Environmental, Mechanical and Cleaning

There were no hardware changes made to the subject device from the previous clearance (K223721); therefore, the testing from the previous clearance was leveraged to support the subject device met the special controls of product code QYU, and acceptability of the electrical safety, environmental, mechanical, and cleaning properties of the subject device.

Software Verification and Validation Testing

As there were no software changes made to the subject device from the previous clearance (K223721), the software testing from the previous clearance was leveraged to support the software verification and validation.

Wireless Testing

As there were no changes made to the subject device from the previous clearance (K223721), no new wireless testing was included as part of this submission.

Cybersecurity Testing

As there were no changes made to the subject device that affects cybersecurity, no new additional cybersecurity testing was included as part of this submission.

Human Factors and Usability Testing

The human factors and usability validation testing was performed in accordance with the FDA Guidance, *Applying Human Factors and Usability Engineering to Medical Devices, February 3, 2016,* and FDA

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Guidance, *Self-Selection Studies for Nonprescription Drug Products, April 2013*, to support the acceptability of the human factors and usability risks of the Masimo Stork when used by OTC caregivers without clinician intervention.

The HF validation testing followed a two-part process, where the first part was the identification of the intended user participants using a self-selection process and the second part used the intended user participants in the validation of the device. The HF validation of the device comprised of simulated use testing and knowledge task evaluations, which were conducted using self-selected participants. A supplemental knowledge task testing was performed that evaluated the understanding of the information provided as part of the Masimo Stork operator's manual.

The results of the human factors and usability evaluation supported the acceptable human factors and usability risks by intended users in the home environment for over-the-counter use.

Clinical Testing

To support the performance of the Masimo Stork, three clinical studies were performed. The first study supported the equivalence of the performance of the Masimo Stork to the FDA cleared RD SET Adhesive sensor (K191059). This testing included data from 30 subjects of light (14) and dark (16) skin pigments undergoing desaturation in accordance with ISO 80601-2-61. The results of the testing supported the equivalence of the Masimo Stork to the cleared reference RD SET Adhesive sensor (K191059). The results are summarized below:

Bias	MAB	Precision	A_{RMS}	LOA	Nsubj	Npairs
0.47	0.94	1.15	1.24	[-1.78, 2.71]	30	1848

The second study was a convenience sample study that was performed to support the form, fit, and function of the Masimo Stork in its indicated population. The study included 42 infants and neonates across different skin pigmentations (22 dark, 20 light), ages, and weights under a doctor's visit. Subjects were classified as light, medium, and dark based upon their Massey-Martin scores. Subjects with a Massey score of 1-3 were classified as "Light", 4-6 classified as "Medium" and 7-10 as "Dark". The overall performance of the Masimo Stork was 0.94 % Crms. The breakdown of the performance for light, medium, and dark subjects is provided below:

Pigmentation	Bias	Precision	C_{RMS}	LOA	Nsubj	Npairs
Dark (Massey 7-10)	0.11	0.77	0.78	[-1.40, 1.62]	6	2698
Medium (Massey 4-6)	-0.04	1.00	1.00	[-2.00, 1.92]	14	8395
Light (Massey 1-3)	-0.24	0.90	0.93	[-1.99, 1.52]	22	14879

The third study was an overnight at-home 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 performed to support the prolonged use of the device in the intended home environment. The data also supported the

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acceptability of Masimo Stork in providing good availability of the monitoring throughout its use (99.7% under low motion conditions).

The performance testing results support the substantial equivalence of the subject device.

6 Conclusion

Based on the data provided as part of this submission, the subject device, Masimo Stork, was found to be substantially equivalent to the predicate device.