July 22, 2022

MedWand Solutions, Inc.
% Natalie Kennel
RA/QA Consultant
NJK & Associates, Inc.
13721 Via Tres Vista
San Diego, California 92129

Re: K212975
Trade/Device Name: MedWand™ Device
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI, DQA, FLL, DQD, ERA
Dated: June 20, 2022
Received: June 21, 2022

Dear Natalie Kennel:

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,

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)*
K212975

Device Name
MedWand™ Device

Indications for Use *(Describe)*
The MedWand™ Device, in combination with the MedWand™ Software Application installed on an attached mobile device or computing system, is an intermittent vital sign measuring and examination system intended to collect, record, and display the following information:

- Oxygen saturation (SpO2),
- Pulse rate (PR),
- Infrared body temperature (TEMP)
- Amplified auscultation sounds filtered for heart, lungs, and abdomen (STETH)
- Photographs of areas needing assessment (CAMERA)

The device is intended for use by adult lay users independently or guided by a health care professional (HCP) in home and non-acute clinical environments.
The MedWand™ Device is intended for use by trained adults only who can use smart phones, tablets, or computers proficiently.
Collected information is not intended for self-diagnosis. Interpretation and assessment of results should be performed by an HCP. Collected information can be provided to a HCP when used as a standalone device.
Additionally, the MedWand™ Device can integrate with external data communications systems (not part of the MedWand™ Device) through a programming interface. This integration will facilitate interactions between the lay user and HCP for telemedicine. The device is intended for spot-checking and does not have continuous monitoring capability or alarm features.

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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510(k) Summary

Sponsor: MedWand Solutions, Inc.
23162 Arroyo Vista
Rancho Santa Margarita, CA 92688 USA

Contact Person: Ms. Natalie J. Kennel
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Date Prepared: July 19, 2022

DEVICE INFORMATION:

Proprietary Name: MedWand™ Device
Common Name: Monitor, Physiological, Patient (without Arrhythmia Detection or Alarms)
Classification: Class II
Product Codes: MWI, DQA, FLL, DQD, ERA
Regulations: 21 CFR 870.2300, 21 CFR 870.1875
Classification Panel: Cardiovascular

INDICATIONS FOR USE:

The MedWand™ Device, in combination with the MedWand™ Software Application installed on an attached mobile device or computing system, is an intermittent vital sign measuring and examination system intended to collect, record, and display the following information:
• Oxygen saturation (SpO_2),
• Pulse rate (PR),
• Infrared body temperature (TEMP)
• Amplified auscultation sounds filtered for heart, lungs, and abdomen (STETH)
• Photographs of areas needing assessment (CAMERA)

The device is intended for use by adult lay users independently or guided by a health care professional (HCP) in home and non-acute clinical environments. The MedWand™ Device is intended for use by trained adults only who can use smart phones, tablets, or computers proficiently. Collected information is not intended for self-diagnosis. Interpretation and assessment of results should be performed by an HCP. Collected information can be provided to an HCP when used as a standalone device.

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For prescription use only.

PREDICATE DEVICES:

The Sponsor selected the following predicate and reference devices for the MedWand™ Device using the FDA Guidance "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]: Guidance for Industry and Food and Drug Administration Staff", issued on July 28, 2014.

Table 1 Predicate and Reference Device Information

510(k)	Product Name	510(k) Holder	Clearance Date	Scope of safety and effectiveness comparison
K210086	Vitals360® Multi-Vitals Mobile Monitor	VoCare, Inc.	May 20, 2021	Primary predicate (covers all functions but stethoscope)
K210736	Doctorgram Stethoscope DES I	GV Concepts	July 27, 2021	Secondary predicate (covers stethoscope function)
K181352	Loop System	Spry Health	March 29, 2019	Reflectance sensor geometry for SpO_2
K011291	Exergen TAT thermometer	Exergen	July 12, 2001	Reference clinical thermometer (same reference body site – rectum)

PRODUCT DESCRIPTION:

The MedWand™ Device is a handheld telemedicine device that allows measurement of SpO_2, pulse rate, and stethoscope along with a camera. The device is intended to be used by lay people or clinical personnel. The patient applies their finger to the sensor on the top of the device designed for measuring SpO_2 and pulse rate. The thermometer is a non-contact IR thermometer that is pointed to the patient's forehead. The camera can be pointed to the particular body part at the (remote) Health Care Professional's (HCP) direction. The stethoscope is contacted directly to the patient's chest or abdomen to provide auscultation sounds to the (remote) HCP.

The MedWand™ Device works as part of the MedWand™ Ecosystem. The MedWand™ Ecosystem consists for following elements:

1. MedWand™ Device including its embedded firmware – This device is provided to the patient or other user who is physically present with the patient.
2. USB-C cable – provided with the device. This cable physically connects the MedWand™ Device to the mobile device or computing platform to provide power, communications, and control for the MedWand™ Device
3. Client App Software – Proprietary software that is provided to the patient or user to run on their mobile device or computing platform (MCP). This software is available for both Windows-based and Android-based devices. This software supports the local operation of the MedWand™ Device and the use of the device in the context of a telemedicine system. This software contains the user interface to the MedWand™ Device. This software provides the user with the concept of a session in which the user activates one or more sensors, collects readings for temperature and pulse oximeter, photos from the camera, and recordings from the stethoscope.
4. Device Communications Module (DCM) – The DCM runs on the MCP incorporated as a library in the Client App. The DCM manages the serial communications between the MedWand™ Device and MCP. The DCM is also known as the Software Developer's Kit (SDK), as it provides a controlled programming interface to enable integration with third-party telemedicine systems.
5. A mobile device (e.g., laptop, tablet or smartphone) or computing platform (laptop or computer) (collectively Mobile Computing Platform (MCP)) – The MCP is supplied by the patient or user, not by MedWand. The Client App proprietary software runs the MCP. The MCP is not part of the medical device.
6. A clinician receiving platform located in a clinical environment (e.g., a PC at the clinic, not supplied by MedWand and not part of the medical device). As described in the cited FDA guidance, this platform and any clinician interface are not part of the medical device.
7. Commercial Telemedicine systems – provides real-time voice and video communications between the HCP and the MedWand™ Device user (as patient) in a virtual live visit. These external software systems would be classified as Medical Device Data Systems, which FDA no longer considers medical devices.

SUBSTANTIAL EQUIVALENCE

The Sponsor has compared the technical and performance characteristics of the subject and predicate devices in a substantial equivalence analysis in Table 2.

Table 2 Comparison to Predicate Device(s)

Characteristic	Subject Device – MedWand™ Device	Primary Predicate - Vitals 360 (K210086)	Secondary Predicate - doctorgram™ Stethoscope DES-I (K210736)	Comparison Evaluation
Applicant	MedWand Solutions, Inc.	VoCare, Inc.	GV Concepts	N/A
Classification Regulation	21 CFR 870.2300 21 CFR 870.1875	21 CFR 870.2300	21 CFR 870.1875	Subject device covered by combination of predicates, with secondary predicate covering the stethoscope.
Classification and Code	Class II MWI, DQA, DQD, FLL, ERA	Class II MWI, DQA, DSH, DXN, FLL	Class II DQD	Subject device covered by combination of predicates. Subject device does not have NIBP so DXN code is not applicable. Secondary predicate covers DQD. ERA – 510(k) exempt.
Common name	Multi-function vital signs device (patient monitor)	Multi-function vital signs device (patient monitor)	Electronic stethoscope	Subject device and primary predicate are the same. The secondary predicate covers the stethoscope function.
Intended Use	Multi-function device that measures, displays, records, and provides vital signs in home and non-acute clinical environments and to remote HCP	Multi-function device that measures, displays, records, and provides vital signs in home and non-acute clinical environments and to remote HCP	Electronic stethoscope that measures, records, and provides these sounds to remote HCP	Subject device and primary predicate have same intended use. Secondary predicate covers the same intended use but only with a stethoscope.

Characteristic	Subject Device – MedWand™ Device	Primary Predicate - Vitals 360 (K210086)	Secondary Predicate - doctorgram™ Stethoscope DES-I (K210736)	Comparison Evaluation
Indications for Use	The MedWand™ Device, in combination with the MedWand™ Software Application installed on an attached mobile device or computing system, is an intermittent vital sign measuring and examination system intended to collect, record, and display the following information: Oxygen saturation (SpO_2) Pulse rate (PR), Infrared body temperature (TEMP), Amplified auscultation sounds filtered for heart, lungs, and abdomen (STETH), Photographs of areas needing assessment (CAMERA). The device is intended for use by adult lay users independently or guided by a health care professional (HCP) in home and non-acute clinical environments. The MedWand™ Device is intended for use by trained adults only who can use smart phones, tablets, or computers proficiently. Collected information is not intended for self-diagnosis. Interpretation and assessment of results should be performed by an HCP. Collected information can be provided to an HCP when used as a standalone device. Additionally, the MedWand™ Device can integrate with external data communications systems (not part of the MedWand™ Device) through a programming interface. This integration will facilitate interactions between the lay user and HCP for telemedicine. The device is intended for spot-checking and does not have continuous monitoring capability or alarm features.	Vitals360® device is intended to be used for measuring, displaying, reviewing, and storing of non-invasive blood pressure (NIBP), non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate (PR), forehead temperature (TEMP), ECG, weight and height in adults no less than 18 years of age. This VITALS360® device is intended for use by trained adults only who can use smartphones proficiently. This VITALS360® device is intended for use in a clinical or home environment. This VITALS360® device is a reusable device following thorough cleaning between uses.	The doctorgram™ Stethoscope DES-I is an electronic stethoscope that enables amplification, filtering, and transmission of auscultation sound data (heart, lungs, bowel, arteries, and veins), whereby a clinician at one location on network can listen to the auscultation sounds of a patient on site or at a different location on the network. The doctorgram™ Stethoscope **DES-I** is intended for use on pediatric and adult patients. The doctorgram™ Stethoscope DES-I is intended to be used by professional users in a clinical environment or by lay users in a nonclinical environment. The device is not intended for self-diagnosis.	Subject device and primary and secondary predicates have similar indications for use in regard to users and use environment. Both subject and primary predicate provide the functions of temperature, SpO_2, and pulse rate.. The primary predicate has functions for capturing NIBP, ECG, weight, and height, which the subject device does not do. The subject device and secondary device have a stethoscope function. Subject device is substantially equivalent to the predicate devices' indications for use.

Characteristic	Subject Device – MedWand™ Device	Primary Predicate - Vitals 360 (K210086)	Secondary Predicate - doctorgram™ Stethoscope DES-I (K210736)	Comparison Evaluation
General Device Characteristics				
Parameters Monitored	Blood oxygen saturation (SpO_2) and pulse rate (PR) non-invasively by the photoelectric method. Body temperature (TEMP) by the infrared radiation energy technology.	Blood oxygen saturation (SpO_2) and pulse rate (PR) non-invasively by the photoelectric method. Non-invasive blood pressure (NIBP, the pressures of systolic and diastolic) by the oscillating method. Body temperature (TEMP) by the infrared radiation energy technology. Additionally, it can record single lead ECG signal.	Amplified auscultation sounds filtered for heart, lungs, abdomen, and arteries and veins	Subject device and primary device both can measure SpO_2, PR, and TEMP. Subject device and secondary device both can measure amplified auscultation sounds with stethoscope.
Patient population	Adults	Adults	Adults	Same
Use Environment	Home use or non-acute clinic	Home use or non-acute clinic	Home use or non-acute clinic	Same
Rx or OTC	Rx	Rx	OTC	Subject device and primary predicates are both prescription use only.
Platform for software	Windows based computer, laptop or Android tablet or smartphone	Smart phone or tablet (iPhone or Android)	Mobile computing platform with iOS smartphone or tablet	Similar. Subject device has a client app software for both Windows and Android based computing platforms whereas primary predicate has only iOS- and Android-based capabilities, and secondary predicate has only iOS. Differences do not raise different issues of safety or effectiveness.
Power Supply	Supplied by the patient-supplied mobile computing platform via USB cord	Battery or AC	Battery	Different: Subject device receives power from computing platform. Subject and both predicates meet electrical safety, so this difference does not raise different issues of safety or effectiveness.
Power requirement	5 V, 2.0A	(100-240) VAC, 50/60Hz, 0.5A, Rechargeable lithium battery, 3.7VDC	Rechargeable lithium battery, 3.7VDC	Similar: Subject and both predicates are low voltage, low power requiring devices.

Characteristic	Subject Device – MedWand™ Device	Primary Predicate - Vitals 360 (K210086)	Secondary Predicate - doctorgram™ Stethoscope DES-I (K210736)	Comparison Evaluation
Connection	USB Type C cord (included)	USB Type C or Bluetooth Smart wireless data link	Bluetooth Smart wireless data link (USB Type C for recharging battery only)	Similar: Subject and primary predicate can be connected by USB. Both predicates also have wireless connections.
Alarm	No alarms	No alarms	No alarms	Same
Use Life	3 years	3 years	Not stated in 510(k) summary or user manual	Same: Subject and primary predicate are the same.
Physical dimension (mm) / weight (kg)	H x W x L: 2.40in x 2.5in x 5.00in (61 x 64 x 127mm)	145mm (L) x 80mm (W) x 25mm (H) (w/o NIBP cuff)	Not stated (from User Manual and website pictures – about 3 x 6 x 3 in.)	Similar: Subject and both predicates are similar sizes.
Weight	5.75oz (163g)	8.8 oz (250g) (w/o NIBP cuff)	Not stated	Similar: Subject and primary predicate are similar.
Display	Display on patient-supplied mobile computing platform (computer, laptop, tablet, smartphone)	3.66 inch	Display on patient-supplied tablet or smartphone	Similar. Subject device can be displayed on a laptop or other computer screen, thereby providing even larger display
Type, Degree of protections against electric shock	Type BF applied part	Class II with internal electric power supply. SpO_2/NIBP/TEMP: Type BF applied part.	Type BF	Same
Operating Temperature	61°F to 104°F (16°C to 40°C)	68°F to 82.4°F (20°C to 28°C) (TEMP, NIBP) 51°F to 95°F (5°C to 35°C) (ECG, SpO_2)	50°F to 104°F (10°C to 40°C)	Subject device operating range is wider than primary predicate range, particularly for TEMP. Secondary predicate has a lower end of operating temperature but not necessary for home use.
Operating RH	20% to 95% non-condensing	40% to 70%	0% to 90%	Ranges are similar with subject device and secondary device being wider than primary predicate. Subject device range sufficient and more appropriate for home environment.

Characteristic	Subject Device – MedWand™ Device	Primary Predicate - Vitals 360 (K210086)	Secondary Predicate - doctorgram™ Stethoscope DES-I (K210736)	Comparison Evaluation
Operating Altitude	Sea level to at least 3,000 m (~10,000 ft)	70 kPa to 106 kPa	1 atm	Subject and primary predicate are same (stated differently), and both meet home use standard.
Storage Temperature	-4°F to 122°F (-20°C to 50°C)	-4°F to 140°F (-20°C to 60°C)	-40°F to 131°F (-40°C to 55°C)	Similar, differences are slight and no impact on device use
Storage RH	5% to 95% non-condensing	10% to 95%	15% to 93%	Similar, differences are slight and no impact on device use
Splash/Water/ Dust Ingress	IP22 under IEC 60529	IP22 under IEC 60529	Not stated	Same
Electric Safety & EMC Standard Applied	ANSI/AAMI/IEC 60601-1:2005 +C1:2006 +C2:2007+A1:2012 IEC 60601-1-2:2014 IEC 60601-1-11:2015	IEC 60601-1:2005 +C1:2006 +C2:2007+A1:2012 IEC 60601-1-2:2014 IEC 60601-1-11:2015	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11	Same (note: secondary predicate didn't list the years but assume they are the same given it's a 2021 clearance)
Pulse Oximetry Function				
Scientific Principle	Detection of light collected from LEDs of varying wavelengths through blood to measure blood oxygen saturation based on amount of light absorbed by hemoglobin in the blood.	Detection of light collected from LEDs of varying wavelengths through blood to measure blood oxygen saturation based on amount of light absorbed by hemoglobin in the blood.	N/A	Same
Sensor geometry	Reflectance	Transmittance	N/A	Different: Both devices meet the particular standard. Reference predicate K181352 with reflectance sensor geometry
SpO_2 measurement range & accuracy	Displayed range: 70%~100% ±2% (during 90~100%), ±3% (during 70~89%)	Displayed range: 70%~100% ±2% (during 90~100%), ±4% (during 70~89%)	N/A	Similar, subject device and predicate device have same range, both meet standard, and subject device meets FDA guidance, which is more stringent.
Pulse rate measurement range	25 to 200 bpm	30 to 150 bpm	N/A	Similar, subject device is slightly wider range.
Pulse rate accuracy	± 2 bpm or ± 2% (whichever is greater)	± 2 bpm or ± 2% (whichever is greater)	N/A	Same

Characteristic	Subject Device – MedWand™ Device	Primary Predicate - Vitals 360 (K210086)	Secondary Predicate - doctorgram™ Stethoscope DES-I (K210736)	Comparison Evaluation
Particular Standard	ISO 80601-2-61:2017	ISO 80601-2-61:2017	N/A	Same
Thermometer Function				
Scientific principle	Non-contact infrared technology	Non-contact infrared technology	N/A	Same
Measuring site	Forehead skin over temporal artery	Forehead skin over temporal artery	N/A	Same
Reference Body site	Rectum	Not stated in 510(k) summary or User Manual	N/A	Unknown if different. Reference predicate: Exergen K011291 used for reference clinical thermometer in clinical study. Subject and reference predicate have same reference body site -rectum.
Operating mode	Adjusted mode: Device automatically converts surface IR temp to predicted body temp	Adjusted mode: Device automatically converts surface IR temp to predicted body temp	N/A	Same
Unit of Measurement	°C or °F	°C or °F	N/A	Same
Temperature resolution	0.1°F or °C	0.1°F or °C	N/A	Same
Temperature measurement range (body)	93°F~107.6°F (33.9°C ~42.0°C)	93.2°F~109.4°F (34.0°C ~43.0°C)	N/A	Subject and primary predicate have slightly different body temperature measurement ranges, but subject range well covers any expected body temperature.
Temperature measurement accuracy	± 0.5°F (± 0.3°C)	± 0.5°F (± 0.3°C)	N/A	Same
Particular Standard Applied	ISO 80601-2-56:2017	ISO 80601-2-56:2017	N/A	Same
Stethoscope Function				

Characteristic	Subject Device – MedWand™ Device	Primary Predicate - Vitals 360 (K210086)	Secondary Predicate - doctorgram™ Stethoscope DES-I (K210736)	Comparison Evaluation
Frequency response range	5Hz to 1.5kHz	N/A	20 Hz to 2kHz	Different: Subject and predicate have some minor differences in frequency range, but these differences do not raise different issues of safety and effectiveness.
Selectable audio filters	Heart (low pass), Lungs (high pass), and Abdomen (wide band pass)	N/A	Heart, Lungs, Bowels (Abdomen), Arteries and veins	Similar: predicate offers one more filter than subject device.
Signal Input Method	Sound waves collected via transducer electro microphone	N/A	Sound waves collected via transducer electro microphone	Same
Audio Output Method	Headphones recommended	N/A	3.5mm earbud headphone	Same
Data storage	Recorded in MedWand application as WAV file	N/A	Transmitted wirelessly	Similar
Biological Safety				
Materials	Patient & user contact surfaces: polycarbonate/polycarbonate-polybutylene terephthalate blend	Not stated	Body: ABS (Acrylonitrile Butadiene Styrene)	Similar materials - thermoplastics; differences do not raise different issues of safety or effectiveness (all meet biocompatibility).
Biocompatibility for patient contacting areas	Biocompatible according to: ISO 10993-1 ISO 10993-5 ISO 10993-10	Biocompatible according to: ISO 10993-1 ISO 10993-5 ISO 10993-10	Biocompatible according to: ISO 10993-1 ISO 10993-5 ISO 10993-10	Same
Cleaning/ Disinfection	Clean/disinfect between uses and patients. (4 commonly available agents recommended)	Clean/disinfect between uses and patients (recommends 70% ethanol)	Clean/disinfect between uses and patients (recommends 70% ethanol)	Same. Subject device recommends 4 options instead of 1 for convenience
Sterility	Non-sterile and not intended to be sterilized	Non-sterile and not intended to be sterilized	Non-sterile and not intended to be sterilized	Same

PERFORMANCE DATA

The Sponsor subjected the MedWand™ Device to design verification and validation testing for electrical safety, electromagnetic compatibility, software V&V, system/bench testing, and biocompatibility. All design control activities were done within the context of the risk management process. These tests verified and validated the proper operation of the system. All patient-contacting components and accessories have been tested to demonstrate appropriate biocompatibility. No part of the system components or accessories are provided sterile or can be sterilized. Cleaning and disinfection instructions are justified and are included in the labeling for the system and accessories. All non-clinical testing required for demonstrating compliance to the applicable particular standards has been successfully conducted. Human factors engineering and usability were evaluated and improved within a risk management process, culminating in a device which can be used safely and effectively according to the intended uses.

CLEANING, DISINFECTION & SHELF-LIFE TESTING

The MedWand™ is a home-use reusable device. The device is not provided sterile and is not intended to be sterilized by users. The device is intended to be cleaned and disinfected between uses and users. Four common EPA-certified cleaning/disinfecting agents that are readily available in the home have been specified for this cleaning/disinfection step.

The Sponsor has validated that the MedWand™ Device can tolerate repeated applications of all four options of cleaning/disinfection agents specified in the User Manual.

The product has a low probability of time-dependent degradation and is not provided sterile. Therefore, the MedWand™ Device and its package do not need a shelf life or expiration date.

The Sponsor validated that in its shelf box and shipping box, the MedWand™ Device and its packaging can tolerate the expected shipping stresses to get the device directly to home use customers.

The User Manual warns users against use of a damaged device and to inspect the device for signs of damage before use. The Sponsor also states the expected use life of the device in the User Manual.

BIOCOMPATIBILITY

The Sponsor evaluated device biocompatibility within the risk management framework and in compliance with ISO 10993 standards. This device evaluation included relevant data sources related to biological safety of finished device testing and component material history of safe biological use and testing. This biocompatibility evaluation establishes the biological safety of patient-contacting surfaces of the MedWand™ Device.

SOFTWARE

The software and firmware in the MedWand™ Device and System, including both custom-developed firmware and OTS software, have been verified and validated and have been demonstrated to be safe and effective for its intended use. The software is a Moderate Level of Concern (LOC) per FDA guidance. All required items related to software as required by FDA guidance for moderate LOC have been included in this submission.

ELECTRICAL SAFETY & EMC

The MedWand™ Device complies with all the medical electrical safety and electromagnetic compatibility requirements of IEC 60601 3.1 edition standards, including the ANSI/AAMI/ES60601 with the U.S. deviations, ANSI/AAMI/IEC 60601-1-11:2015, and the 4th edition of collateral standard for EMC, IEC 60601-1-2:2014. The requested information from FDA guidance to support a claim of EMC of electrically powered medical devices has been provided.

ANIMAL STUDIES

No animal studies were conducted to demonstrate performance or substantial equivalence.

CLINICAL STUDIES

Two clinical studies cohorts were conducted and have been included in this submission to demonstrate substantial equivalence. In all cases, the clinical studies were conducted to evaluate one or more MedWand™ Device functions in comparison to cleared, well-established medical devices which perform that function or reference method following FDA recognized standards where applicable.

One clinical study, a controlled hypoxia or desaturation study, was conducted to provide human validation data of pulse oximeters according to ISO 80601-2-61:2017 and FDA guidance on pulse oximeters. The study included fourteen (14) healthy volunteer subjects, ages 21- 40 and 6/14 identified as male (42%) with a range of ethnicities. The 14 subjects had a range of skin tones, including at least 28% (4/14) with dark skin tones, thus exceeding the requirements in the standard and FDA guidance of at least 2 or 15%. Controlled hypoxia was induced with a breath-by-breath respiratory gas analysis and a computer program that permits the inspired gas mixture to be adjusted to achieve a level of lung alveolar gas that will achieve the desired degree of hypoxia. Oxygen saturation was determined once with air breathing and then at one of the six (6) levels, e.g., 94%, 90%, 85%, 80%, 75%, and 70% saturation for about 30-60 seconds at each level. During the study, two arterial blood samples were obtained from an indwelling catheter 30 seconds apart at the end of each hypoxic plateau. A total of 327 blood samples were obtained at the saturation plateaus across the span. The blood samples were measured for SaO2 on a co-oximeter.

The MedWand pulse oximeter data were taken as 5-second averages at each plateau to arterial blood analysis for comparison. According to equation 1 in ISO 80601-2-61:2017 [1], ARMS for the MedWand SpO_2 was calculated for each range of the following SaO2 ranges of 70-80%, 80-90%, 90-100% and 70-100%. The results were 3.00%, 1.62%, 1.37%, and 2.05%, respectively. The MedWand ™ Device met the more stringent required acceptance criteria from the FDA guidance for reflectance pulse oximeters.

To validate the MedWand™ Device thermometer function to a well-established reference clinical thermometer according to ISO 80601-2-56:2017 and to provide additional clinical agreement data for the MedWand™ Device pulse oximeter function with a cleared, well-established pulse oximeter, one hundred fifty-eight (158) subjects from an outpatient health clinic were enrolled. Subjects ranged in age from 18 to 81 years old with median of 35 and mean

of 37 and 64/158 (41%) identified as male. Skin tones ranged from 1 to 6 out of 6 (dark) with a median of 2. Fifty-nine (59) of the one hundred fifty-eight (158) subjects (37%) presented febrile symptoms, thus meeting the requirement of 30-50% being febrile from the associated particular standard for thermometers. Following this particular standard, the first MedWand temperature replicate was compared to the reference clinical thermometer to evaluate accuracy. The three (3) replicates of MedWand temperature were used to calculate the clinical repeatability. This data was used to calculate clinical bias, limits of agreement, and clinical repeatability, according to the particular standard for thermometers. These data are published in the device user manual. The results are similar to other published temperature data for IR thermometers.

The MedWand Device SpO_2 and pulse rate measurements were compared to the cleared pulse oximeter using root-mean-square (RMS) calculation to provide additional clinical agreement data in humans. These results were comparable to other results published for similar devices.

CONCLUSION

The Sponsor believes that the MedWand™ Device is substantially equivalent to its primary and secondary predicate devices. The intended use, general design, and performance characteristics are the same or similar. The primary predicate covers all of the functions except the stethoscope, and the secondary predicate covers the stethoscope function. The minor differences in choice of materials, specifications and characteristics do not raise different issues of safety and effectiveness.