September 25, 2019

Digicare Biomedical Technology, Inc.
Pedro Miranda
VP of Software Engineering
107 Commerce Rd.
Boynton Beach, Florida 33426

Re: K183687
Trade/Device Name: LifeWindow LW8 Lite
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI, DRT, DSB, BZQ, DXN, DSK, FLL, DQA, DPZ, CCK, CCL
Dated: August 21, 2019
Received: August 23, 2019

Dear Pedro Miranda:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for LT Stephen Browning
Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

Indications for Use

510(k) Number *(if known) K183687*

Device Name
Digicare Biomedical LifeWindow™ LW8 Lite multi-parameter patient monitor and accessories

Indications for Use *(Describe)*
The LifeWindow™ LW8 Lite is a multi-parameter physiological patient monitor indicated for continuous measurement of the following parameters:

- ECG waveforms from 3 or 5 lead measurements
- Heart Rate (from ECG)
- Non-invasive blood pressure (NIBP) automatically measures systolic and diastolic pressure and pulse rate, while calculating mean arterial pressure (MAP). The equation used to calculate MAP provides an approximate value
- End-tidal CO2 concentration (EtCO2) – Mainstream or Sidestream
- Inspired CO2 concentration (insCO2) – Mainstream or Sidestream
- Fractional Inspired Oxygen (FiO2)
- Acoustic Respiration Rate (RRa)
- Respiration Rate (from bioimpedance or EtCO2 measurement, or RRa)
- Two Temperature channels
- Two Invasive Pressure channels (IP1, IP2)
- Pulse Rate in BPM (from Pulse CO-Oximetry and/or NIBP)
- Pulse CO-Oximetry and pulse rate – the LifeWindow LW8 Lite Pulse CO-Oximeter functions and accessories incorporating Masimo technology are indicated for the continuous noninvasive monitoring of the following parameters during both no motion and motion conditions, and for patients who are well or poorly perfused:
  - o Functional oxygen saturation of arterial hemoglobin (SpO2)
  - o Carboxyhemoglobin saturation (SpCO)
  - o Methemoglobin saturation (SpMet)
  - o Total hemoglobin concentration (SpHb)

The defined patient population is adult through neonatal patients with appropriate accessories. The monitor displays a range of physiological waveforms and indices and provides alarms.
The LifeWindow™ LW8 Lite multi-parameter patient monitor may be used in hospitals, hospital-type facilities, surgery centers, and emergency facilities. For professional use only. It is not intended for helicopter transport, hospital ambulance, or home use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary in accordance with 21 CFR 807.92

(a) (1) **Submitted by:**

Digicare Biomedical Technology, Inc.
107 Commerce Rd.
Boynton Beach
Florida 33426
Tel.: +1 (561) 689-0408
Fax: +1 (561) 689-0021
pedro(at)digicarebiomedical.com

Contact Person: Mr. Pedro Miranda

Position/Title: Vice President of Software Engineering

Date of Preparation: September 19, 2019

(2) **Trade Name:** LifeWindow™ LW8 Lite Multi-Parameter Monitor

Common/Classification Name: Monitor, Physiological, Patient

Product Code(s):

Regulation No.	Classification Name	Product Code	Device Class
Main Product Code			
21 CFR §870.2300	Monitor, Physiological, Patient (Without Arrhythmia Detection or Alarms)	MWI	Class II
Subsequent Product Code(s)			
21 CFR § 870.2300	Cardiac monitor (including cardiotachometer and rate alarm) Cardiac monitor	DRT	Class II
21 CFR § 870.2770	Impedance plethysmograph	DSB	Class II
21 CFR § 868.2375	Breathing frequency monitor	BZQ	Class II
21 CFR § 870.1130	Non-invasive blood pressure measurement system	DXN	Class II
21 CFR § 870.1110	Blood pressure computer	DSK	Class II
21 CFR § 880.2910	Clinical Electronic Thermometer	FLL	Class II
21 CFR § 870.2700	Pulse Oximeter	DQA	Class II
21 CFR § 870.2710	Ear Oximeter	DPZ	Class II
21 CFR § 868.1400	Carbon Dioxide Gas Analyzer	CCK	Class II
21 CFR § 868.1720	Oxygen Gas Analyzer	CCL	Class II

(3) **Predicate Device(s):** Substantial Equivalence to:

K Number	Model	Manufacturer
K131898	Biolight A Series and Q Series Patient Monitors	Guangdong Biolight Meditech Co., Ltd.
K122290	EnviteC MySign® O Oxygen Measuring Device	EnviteC-Wismar GmbH
K110028	Radical-7 Pulse CO-Oximeter	Masimo Corporation

Reason for Submission: New Device(s)

(4) **Description of Device:**

The LifeWindow™ LW8 Lite Multi-Parameter Monitor is designed for the measurement and monitoring of multiple physiological parameters simultaneously in a single patient.

LifeWindow™ LW8 Lite Multi-Parameter Monitor is constructed with the following features:

- Compact monitor design in a rugged aluminum chassis
- Integration of cleared vital signs modules
- Patients from neonates through adults
- High Definition 8.4” TFT screen with touch screen operation
- Multi-channel vital signs trace display with variable sweep speeds
- Hardcopy printing via an integrated strip chart or compatible printer
- Waveforms sweep speeds from 6.25mm/s up to 50mm/s
- Mainstream and sidestream Capnography options
- Specification of cleared third-party patient-applied accessories

(5) **Intended use:**

Multi-parameter monitoring of patient vital signs has been a standard of care for over 25 years and is established globally. Multi-parameter patient monitors provide clinicians with a range of continuous physiological measurements with alarms.

The intended use for the LifeWindow™ LW8 Lite Multi-Parameter Monitor is the same as the predicate device: measurement and monitoring of multiple physiological parameters, in an adult through neonatal patient population, with appropriate patient applied accessories. The LifeWindow™ LW8 Lite Monitor is specified for use in professional healthcare environments by clinical staff.

Indications for Use:

The LifeWindow™ LW8 Lite is a multi-parameter physiological patient monitor indicated for continuous measurement of the following parameters:

- ECG waveforms from 3 or 5 lead measurements
- Heart Rate (from ECG)
- Non-invasive blood pressure (NIBP) automatically measures systolic and diastolic pressure and pulse rate, while calculating mean arterial pressure (MAP). The equation used to calculate MAP provides an approximate value.
- End-tidal CO2 concentration (EtCO2) – Mainstream or Sidestream
- Inspired CO2 concentration (insCO2) – Mainstream or Sidestream
- Fractional Inspired Oxygen (FiO2)
- Acoustic Respiration Rate (RRa)
- Respiration Rate (from bioimpedance or EtCO2 measurement, or RRa)
- Two Temperature channels
- Two Invasive Pressure channels (IP1, IP2)
- Pulse Rate in BPM (from Pulse CO-Oximetry and/or NIBP)
- Pulse CO-Oximetry and pulse rate – the LifeWindow LW8 Lite Pulse CO-Oximeter functions and accessories incorporating Masimo technology are indicated for the continuous noninvasive monitoring of the following parameters during both no motion and motion conditions, and for patients who are well or poorly perfused:
    - Functional oxygen saturation of arterial hemoglobin (SpO2)
    - Carboxyhemoglobin saturation (SpCO)
    - Methemoglobin saturation (SpMet)
    - Total hemoglobin concentration (SpHb)

The defined patient population is adult through neonatal patients with appropriate accessories. The monitor displays a range of physiological waveforms and indices and provides alarms.

The LifeWindow LW8 Lite multi-parameter patient monitor may be used in hospitals, hospital-type facilities, surgery centers, and emergency facilities. For professional use only. It is not intended for helicopter transport, hospital ambulance, or home use.

Prescription device.

(6) Technological Characteristics:

LifeWindow™ LW8 Lite Multi-Parameter Monitor utilize the same technological principles as the predicate devices to measure patient vital signs: the incorporation of physiological measurement modules, with appropriate accessories. Refer to the following comparison table:

Comparison of Technological Features to Predicate Devices:

Product/Feature	LifeWindow™ LW8 Lite Multi-Parameter Monitor	A3 Series Multi-Parameter Monitor	MySign® O Oxygen Measuring Device	Radical-7 Pulse CO-Oximeter	Comparison Analysis
Manufacturer	Digicare Biomedical Technology, Inc.	Guangdong Biolight Meditech Co., Ltd.	EnviteC-Wismar GmbH by Honeywell	Masimo Corporation	
Model Number(s)	LW8	A3 Series	MySign® O	Radical-7	
510(k) Number	(*pending - this submission*)	K131898	K122290	K110028	
Application/Intended use:	Monitor multiple physiological parameters	Monitor multiple physiological parameters	Monitor fractional inspired Oxygen (FiO2)	Monitor pulse co-oximetry and acoustic respiration rate (RRa)	Equivalent monitoring function for specified parameters and sites

Indications for use:	The LifeWindow™ LW8 Lite is a multi-parameter physiological patient monitor indicated for continuous measurement of the following parameters: • ECG waveforms from 3 or 5 lead measurements • Heart Rate (from ECG) • Non-invasive blood pressure (NIBP) automatically measures systolic and diastolic pressure and pulse rate, while calculating mean arterial pressure (MAP). The equation used to calculate MAP provides an approximate value. • End-tidal CO2 concentration (EtCO2) – Mainstream or Sidestream • Inspired CO2 concentration (insCO2) – Mainstream or Sidestream • Fractional Inspired Oxygen (FiO2) • Acoustic Respiration Rate (RRa) • Respiration Rate (from bioimpedance or EtCO2 measurement, or RRa) • Two Temperature channels • Two Invasive Pressure channels (IP1, IP2) • Pulse Rate in BPM (from Pulse CO-Oximetry and/or NIBP)	Patient monitors are intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters including ECG (3-lead or 5-lead or 12-lead selectable), arrhythmia detection, ST segment analysis, Heart Rate (HR), Respiration Rate (RESP), Temperature (TEMP), Pulse Oxygen Saturation (SpO2), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), Invasive Blood Pressure (IBP), Carbon dioxide (C02), Anesthetic Gas (AG), Impedance Cardiograph (ICG), Cerebral State Index (CSI), Bispectral Index (HIS), Total Hemoglobin(SpHb), Carboxyhemoglobin (SpCO), and Methemoglobin(SpMet). The arrhythmia detection, ST segment analysis only applied to a single adult patient. The monitors are to be used in healthcare facilities by clinical physicians or appropriate medical staff under the direction of physician. It is not intended for helicopter transport,	This oxygen measuring device MySign® O is designed for continuous or spot monitoring **of** inspired oxygen concentrations in breathing gas. MySign® O can be used for monitoring the breathing gases dispensed by the following devices: Anaesthesia breathing systems Respiratory equipment Infant incubators Oxygen therapy systems The system is suitable for use inside hospitals as well as during transport (except by air), emergencies, and artificial respiration provided at home.	The Masimo Radical 7 Pulse CO-Oximeter and accessories are indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SPO2), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (RRa). The Masimo Radical 7 Pulse CO-Oximeter and accessories are indicated for use with adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are - well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments. In addition, the Masimo Radical 7 Pulse CO-Oximeter and accessories are indicated to provide the continuous non-invasive monitoring data obtained from the Masimo Radical 7 Pulse CO-Oximeter end accessories of functional oxygen saturation of arterial	See above- equivalent monitoring function for specified parameters and sites

	• Pulse CO-Oximetry and pulse rate – the LifeWindow LW8 Lite Pulse CO-Oximeter functions and accessories incorporating Masimo technology are indicated for the continuous noninvasive monitoring of the following parameters during both no motion and motion conditions, and for patients who are well or poorly perfused: ○ Functional oxygen saturation of arterial hemoglobin (SpO2) ○ Carboxyhemoglobin saturation (SpCO) ○ Methemoglobin saturation (SpMet) ○ Total hemoglobin concentration (SpHb) The defined patient population is adult through neonatal patients with appropriate accessories. The monitor displays a range of physiological waveforms and indices and provides alarms. The LifeWindow LW8 Lite multi-parameter patient monitor may be used in hospitals, hospital-type facilities, surgery centers, and emergency facilities. For professional use only. It is not intended for helicopter transport,	hospital ambulance, or home use.		hemoglobin (SpO2) and pulse rate to multi-parameter devices for the display of those devices.	

Product/Feature	LifeWindow™ LW8 Lite Multi-Parameter Monitor	A3 Series Multi-Parameter Monitor	MySign® O Oxygen Measuring Device	Radical-7 Pulse CO-Oximeter	Comparison Analysis
	hospital ambulance, or home use.				
Alarms	YES	YES	YES	YES	Same
Application Site(s)	Patient sites vary by parameter measured	Patient sites vary by parameter measured	Inspired airway path	Pulse co-oximetry site: digit, toe, ear, foot, forehead; acoustic respiration	Equivalent monitoring function at specified sites
Patient Population	Adult through neonatal patients	Adult through neonatal patients; (adults only for arrhythmia and ST segment)	Adult through neonatal patients	Adult through neonatal patients	Equivalent monitoring function, LW8 does not claim Arrhythmia and ST segment.
Cardiac Monitor (ECG)	3/5 Lead	3/5/12 Lead	--	--	Equivalent function Claims of the LW8 are within the claims of the predicate.
Detector and Alarm, Arrhythmia	--	Implemented/offered	--	--	Arrhythmia detection not claimed by subject device - claims of the LW8 are within the claims of the predicate
Monitor, ST Segment with Alarm	--	Implemented/offered	--	--	ST Segment monitoring not claimed by subject device - claims of the LW8 are within the claims of the predicate
Impedance respiration	Implemented with ECG	Implemented w/ ECG	--	--	Equivalent function with same technology

Product/Feature	LifeWindow™ LW8 Lite Multi-Parameter Monitor	A3 Series Multi-Parameter Monitor	MySign® O Oxygen Measuring Device	Radical-7 Pulse CO-Oximeter	Comparison Analysis
Acoustic respiration	Masimo (RRa)	--	--	Masimo (RRa)	LW8 Acoustic respiration rate utilizes the Masimo RRa which is the same technology utilized in predicate Radical-7
Invasive Blood pressure	YES	YES	--	--	Equivalent function with same measurement principle
Non-invasive blood pressure	Oscillometric	Oscillometric	--	--	Equivalent function with same technology
Patient Temperature	YSI 400	YSI 400	--	--	Equivalent function with same measurement principle
Pulse co-oximetry	Masimo technology	Masimo technology	--	Masimo technology	Equivalent function with same technology
Carbon Dioxide Gas Analyzer	Mainstream and sidestream	Mainstream and sidestream	--	--	Equivalent function with same technology
Inspired Oxygen (FiO2)	EnviteC technology	Paramagnetic	EnviteC technology	--	Same as the MySign O predicate device. Primary predicate A3 offers a different type of technology for measuring FiO2.
Enflurane gas analyzer	--	Implemented/offered	--	--	LW8 does not measure nor claim anesthetic agents,
Halothane gas analyzer	--	Implemented/offered	--	--	

Product/Feature	LifeWindow™ LW8 Lite Multi-Parameter Monitor	A3 Series Multi-Parameter Monitor	MySign® O Oxygen Measuring Device	Radical-7 Pulse CO-Oximeter	Comparison Analysis
Nitrous Oxide gas analyzer	--	Implemented/offered	--	--	therefore there are no claims related to these gas measurements - claims of the LW8 are within the claims of the predicate
Cerebral State Index (EEG)	--	Implemented/offered	--	--	LW8 does not measure nor claim cerebral state index (CSI) by EEG method, are no claims related to this parameter measurements - claims of the LW8 are within the claims of the predicate
Environment of Use	May be used in hospitals, hospital-type facilities, surgery centers, and emergency facilities. For professional use only. Not intended for helicopter transport, hospital ambulance, or home use.	(Professional healthcare environments). not intended for helicopter transport, hospital ambulance, or home use	For use inside hospitals as well as during transport (except by air), emergencies, and artificial respiration provided at home	For use inside hospitals, hospital-type facilities, mobile, and home environments	Both LW8 and primary predicate A3 monitors are specified for professional healthcare facilities, and not transport or home. MySign® O and Radical-7 use includes home and transport environments.
Scenario of Use	Patient connected monitor for continuous monitoring of vital signs with alarms	Patient connected monitor for continuous monitoring of vital signs with alarms	Portable device for continuous monitoring of inspired Oxygen with alarms	Portable device for continuous monitoring of inspired Pulse-CO Oximetry and Breathing Frequency (RRa) with alarms	Same context of use as continuous alarming monitor
Moisture Protection Class	IP21	IPX1	IP54	IPX1	Equivalent to Primary Predicate A3. The LW8 provides higher IP classification than primary predicate.
Classification according to the IEC60601-1					

Product/Feature	LifeWindow™ LW8 Lite Multi-Parameter Monitor	A3 Series Multi-Parameter Monitor	MySign® O Oxygen Measuring Device	Radical-7 Pulse CO-Oximeter	Comparison Analysis
Electrical Protection Class - Mainframe	I	I	II	I	Same electrical protection class as primary predicate
Electrical Protection	CF Defibrillation proof	CF Defibrillation proof	BF	BF	Same protection class for LW8 and primary predicate A3 monitor
Mode of Operation	Continuous	Continuous	Continuous	Continuous	Same
ECG Heart Rate					
Measurement range	10 – 300 BPM (Adult) 10 – 350 BPM (Pedi/Neo)	10 – 300 BPM (Adult) 10 – 350 BPM (Pedi/Neo)	--	--	Same
Resolution	1 BPM	1 BPM	--	--	Same
Accuracy	± 1% or 1 BPM, whichever is greater	± 1% or 1 BPM, whichever is greater	--	--	Same
Resp Rate					
Measurement Range	0 to150 BPM	0 to150 BPM	--	--	Same
Resolution	1 BPM	1 BPM	--	--	Same
Accuracy	±2 BPM or ±2%, whichever greater	±2 BPM or ±2%, whichever is the greater	--	--	Same
NIBP (Suntech)					
Systolic Measurement range （mmHg）	Adult: 40 – 260 Pediatric: 40 – 230 Neonatal: 40 – 130	Adult: 40 – 260 Pediatric: 40 – 230 Neonatal: 40 – 130	--	--	Same
Diastolic Measurement range （mmHg）	Adult: 20 – 200 Pediatric: 20 – 160 Neonatal: 20 – 100	Adult: 20 – 200 Pediatric: 20 – 160 Neonatal: 20 – 100	--	--	Same

Product/Feature	LifeWindow™ LW8 Lite Multi-Parameter Monitor	A3 Series Multi-Parameter Monitor	MySign® O Oxygen Measuring Device	Radical-7 Pulse CO-Oximeter	Comparison Analysis
MAP Measurement range（mmHg）	Adult: 26 – 220 Pediatric: 26 – 183 Neonatal: 26 – 110	Adult: 26 – 220 Pediatric: 26 – 183 Neonatal: 26 – 110	--	--	Same
Pressure Measurement Accuracy	Clinical Accuracy: Meets accuracy requirements of ANSI/AAMI SP10:2002(R)2008, EN1060-4:2004 and ISO 81060-2:2009	± 3 mmHg (± 0.4 kPa) or 2 % of the reading above 200 mmHg for the ambient temperature range of 50°F to 104°F (10°C to 40°C), the humidity range of 15 % to 90 %	--	--	Same
Pressure transducer accuracy	±3mmHg between 0 mmHg and 300 mmHg for operating conditions between 0°C and 50°C.	±3mmHg between 0 mmHg and 300 mmHg for operating conditions between 0°C and 50°C.	--	--	Same
PR range	30 – 220 BPM	30 – 220 BPM	--	--	Same
Pulse Rate Accuracy	2% or 3 bpm, whichever is greater	2% or 3 bpm, whichever is greater	--	--	Same
SpO2 (Masimo) **Pulse CO-Oximetry**					
SpO2					
Measurement range	0 – 100%	0 – 100%	--	0 – 100%	Same
Resolution	1%	1%	--	1%	Same

Product/Feature	LifeWindow™ LW8 Lite Multi-Parameter Monitor	A3 Series Multi-Parameter Monitor	MySign® O Oxygen Measuring Device	Radical-7 Pulse CO-Oximeter	Comparison Analysis
Accuracy	No Motion Adults, Pediatric, Infants: 60 – 80 ± 3% 70 – 100 ± 2% No Motion Neonates: 70 – 100 ± 3% Motion: 70 – 100 ± 3% Low Perfusion: 70 – 100 ± 2% 0% to 69%，unspecified	No Motion Adults, Pediatric, Infants: 60 – 80 ± 3% 70 – 100 ± 2% No Motion Neonates: 70 – 100 ± 3% Motion: 70 – 100 ± 3% Low Perfusion: 70 – 100 ± 2% 0% to 69%，unspecified	--	No Motion Adults, Pediatric, Infants: 60 – 80 ± 3% 70 – 100 ± 2% No Motion Neonates: 70 – 100 ± 3% Motion: 70 – 100 ± 3% Low Perfusion: 70 – 100 ± 2% 0% to 69%，unspecified	Same
Pulse Rate (PR)					
Measurement Range	25 – 240 BPM	25 – 240 BPM	--	25 – 240 BPM	Same
Accuracy	No Motion: ± 3 BPM Motion: ± 5 BPM Low Perfusion: ± 3 BPM	No Motion: ± 3 BPM Motion: ± 5 BPM Low Perfusion: ± 3 BPM	--	No Motion: ± 3 BPM Motion: ± 5 BPM Low Perfusion: ± 3 BPM	Same
Resolution	1 BPM	1 BPM	--	1 BPM	Same
SpCO				--	
Measurement range	0 – 99%	0 – 100%	--	0 – 99%	Same

Product/Feature	LifeWindow™ LW8 Lite Multi-Parameter Monitor	A3 Series Multi-Parameter Monitor	MySign® O Oxygen Measuring Device	Radical-7 Pulse CO-Oximeter	Comparison Analysis
Accuracy	No Motion: Adults, Pediatric, Infants: 1 – 40 ± 3 % ＞40%，unspecified	No Motion: Adults, Pediatric, Infants: 1 – 40 ± 3 % ＞40%，unspecified	--	No Motion: Adults, Pediatric, Infants: 1 – 40 ± 3 % ＞40%，unspecified	Same
SpMet				--	
Measurement range	0 – 99.9%	0 – 100%	--	0 – 99.9%	Same
Accuracy	Adults, Pediatric, Infants, Neonates: 1 – 15 ± 1 % ＞15%，unspecified	0% to 15%：±1% （non-motion conditions） ＞15%，unspecified	--	Adults, Pediatric, Infants, Neonates: 1 – 15 ± 1 % ＞15%，unspecified	Same
Perfusion Index (PI)				--	
Measurement Range	0.02 – 20%	0.05 – 20%	--	0.02 – 20%	Same
Resolution	PI < 1.00: 0.01 PI < 10: 0.1 PI > 10: 1	Information Not Available	--	PI < 1.00: 0.01 PI < 10: 0.1 PI > 10: 1	Same
SpHb				--	
Measurement range	0 – 25 g/dL	0 – 25 g/dL	--	0 – 25 g/dL	Same
Accuracy	Adults, Pediatric: 8 – 17 ± 1 g/dL	8 g/dl to 17 g/dl：±1g/dl（non-motion conditions） ＜8 g/dl or ＞17 g/dl，unspecified	--	Adults, Pediatric: 8 – 17 ± 1 g/dL	Same

Product/Feature	LifeWindow™ LW8 Lite Multi-Parameter Monitor	A3 Series Multi-Parameter Monitor	MySign® O Oxygen Measuring Device	Radical-7 Pulse CO-Oximeter	Comparison Analysis
Resolution	0.1 g/dL	Information Not Available	--	0.1 g/dL	Same
Alarm Range	1.0 – 24.5 g/dL	Information Not Available	--	1.0 – 24.5 g/dL	Same
SpOC				--	
Measurement range	0 – 35 ml/dL	0 – 35 ml/dL	--	0 – 35 ml/dL	Same
Resolution	1 ml/dL	Information Not Available	--	1 ml/dL	Same
Pleth Variability Index (PVI)				--	
Measurement Range	0 – 100%	--	--	0 – 100%	Same as predicate Radical-7, not implemented on primary predicate A3.
Resolution	1 %	--	--	1 %	Same as predicate Radical-7, not implemented on primary predicate A3.
Respiration Rate (RRa)				--	
Measurement Range	4 – 70 bpm	--	--	4 – 69 bpm	Same as predicate Radical-7, not implemented on primary predicate A3.
Accuracy	Adults/Pediatric: 4 – 70 ± 1 BPM	--	--	Adults/Pediatric: 4 – 70 ± 1 BPM	Same as predicate Radical-7, not implemented on primary predicate A3.

Product/Feature	LifeWindow™ LW8 Lite Multi-Parameter Monitor	A3 Series Multi-Parameter Monitor	MySign® O Oxygen Measuring Device	Radical-7 Pulse CO-Oximeter	Comparison Analysis
Resolution	1 BPM	--	--	1 BPM	Same as predicate Radical-7, not implemented on primary predicate A3.
Temperature				--	
Accuracy	Rated Range: 35.0 – 42.0°C (95.0 – 107.6°F): ± 0.3 °C (± 0.5°F) Extended Range: -1.0 – 34.9°C (30.2 – 94.8°F) and 42.1 – 45.0°C (107.8 - 113°F): ± 0.4 °C (± 0.7°F)	Accuracy ±0.1℃ or ±1℉ (exclusive of probe)	--	--	Equivalent Function, LifeWindow complies with current industry standard.
Resolution	0.1°C (0.2°F)	0.1℃ or 1℉	--	--	Same
IBP (Invasive Blood Pressure)				--	
Pressure measurement range	-40 to +300 mmHg	-50 mmHg to +350 mmHg	--	--	Equivalent Function with slightly different range - claims of the LW8 are within the claims of the predicate
Pressure Measurement accuracy	± 4 mmHg or ±4% of the reading, whichever is greater. (Transducer included)	±4 mmHg or ±4% of the reading, whichever is the greater (inclusion of transducer)	--	--	Same
Resolution	1 mmHg	1 mmHg	--	--	Same

Product/Feature	LifeWindow™ LW8 Lite Multi-Parameter Monitor	A3 Series Multi-Parameter Monitor	MySign® O Oxygen Measuring Device	Radical-7 Pulse CO-Oximeter	Comparison Analysis
Mainstream CO2 module (CAPNOSTAT5) Respironics					
Measurement range (EtCO2)	Percent (%): 0 – 19.7 mmHg: 0 – 150 kPa: 0 – 20	0% to 19.7 % 0 mmHg to 150 mmHg	--	--	Same
Resolution (EtCO2)	1 mmHg	0.1% or 1mmHg	--	--	Same
Accuracy (EtCO2)	0 - 40 mmHg ± 2 mmHg 41 - 70 mmHg ± 5% of reading 71 - 100 mmHg ± 8% of reading 101 - 150 mmHg ± 10% of reading	0 - 40 mmHg ± 2 mmHg 41 - 70 mmHg ± 5% of reading 71 - 100 mmHg ± 8% of reading 101 - 150 mmHg ± 10% of reading	--	--	Same
awRR measurement range (Resp Rate)	0 – 150 BPM	0 rpm to 150 rpm	--	--	Same
awRR measurement accuracy (Resp Rate)	± 1 BPM	±1 rpm	--	--	Same
Measurement range (InsCO2)	3 to 50 mmHg	3 to 50 mmHg	--	--	LifeWindow specification is per cleared CO2 module.
Resolution (InsCO2)	1 mmHg	0.1 mmHg 0 to 50 mmHg	--	--	Equivalent Function not offering decimal point resolution

Product/Feature	LifeWindow™ LW8 Lite Multi-Parameter Monitor	A3 Series Multi-Parameter Monitor	MySign® O Oxygen Measuring Device	Radical-7 Pulse CO-Oximeter	Comparison Analysis
Accuracy (InsCO2)	3 - 40 mmHg ± 2 mmHg 41 - 50 mmHg ± 5% of reading	3 - 40 mmHg ± 2 mmHg 41 - 50 mmHg ± 5% of reading	--	--	Same
Respironics CO2 module (LoFlo) Respironics					
Measurement range (EtCO2)	0 – 19.7% 0 – 150 mmHg 0 – 20 kPa	0% to 19.7 % 0 mmHg to 150 mmHg	--	--	Same
Resolution (EtCO2)	1 mmHg	0.1% or 1 mmHg	--	--	Same
Accuracy (EtCO2)	0 - 40 mmHg ± 2 mmHg 41 - 70 mmHg ± 5% of reading 71 - 100 mmHg ± 8% of reading 101 - 150 mmHg ± 10% of reading (when RR ＞ 80 rpm, all the range is ±12% of reading) Gas temperature at 25℃	0 - 40 mmHg ± 2 mmHg 41 - 70 mmHg ± 5% of reading 71 - 100 mmHg ± 8% of reading 101 - 150 mmHg ± 10% of reading (when RR ＞ 80 rpm, all the range is ±12% of reading) Gas temperature at 25℃	--	--	Same
awRR measurement range (Resp Rate)	2 – 150 BPM	2 rpm to 150 rpm	--	--	Same
awRR measurement accuracy (Resp Rate)	± 1 BPM	±1 rpm	--	--	Same

Product/Feature	LifeWindow™ LW8 Lite Multi-Parameter Monitor	A3 Series Multi-Parameter Monitor	MySign® O Oxygen Measuring Device	Radical-7 Pulse CO-Oximeter	Comparison Analysis
Measurement Range (insCO2)	3 to 50 mmHg	3 to 50 mmHg	--	--	Same
Accuracy (InsCO2)	3 - 40 mmHg ± 2 mmHg 41 - 50 mmHg ± 5% of reading	3 - 40 mmHg ± 2 mmHg 41 - 50 mmHg ± 5% of reading	--	--	Same
Resolution (InsCO2)	1 mmHg	0.1 mmHg 0 to 50 mmHg	--	--	Equivalent Function with no decimal point resolution
Resp Rate Resolution	1 BPM	1 BPM	--	--	Same
Inspired Fraction of Oxygen (FiO2)					
Measurement Range	0-100% Oxygen	--	0-100% Oxygen	--	Same
Display Precision (Resolution)	1%	--	0.1%	--	Equivalent Function with no decimal point resolution
Accuracy and Repeatability (Precision)	<1% vol. O_2 if calibrated with 100% vol. O_2	--	<1% vol. O_2 if calibrated with 100% vol. O_2	--	Same

Summary points from the device claims comparison:

- The intended use for the LifeWindow™ LW8 Lite and the primary predicate device Biolight A Series Patient Monitor are the same: multi-parameter patient vital signs monitoring.
- The LifeWindow™ LW8 Lite Monitor does not claim arrhythmia detection & monitoring (product code DSI), ST segment monitoring (product code MLD), nor cerebral state by EEG (product code GWQ). LifeWindow™ LW8 Lite Monitor does not provide support for the measurement of anesthetic agents for halothane product code CBS), enflurane (product code CBQ), nor nitrous Oxide (CBR). The predicate Biolight A Series Patient Monitor does claim these monitoring parameters and classifications. The LifeWindow™ LW8 Lite Monitor utilizes parameter regulatory classifications that are within those utilized by the predicate Biolight A Series Patient Monitor.
- The LifeWindow™ LW8 Lite Monitor and predicate MySign O Oxygen Measuring Device are both indicated for continuous or spot monitoring of inspired oxygen concentrations in breathing gas.
- The LifeWindow™ LW8 Lite Monitor and predicate Masimo Radical-7 Pulse CO-Oximeter are both indicated for the continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SPO2), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (RRa).
- The LifeWindow™ LW8 Lite Multi-Parameter Monitor and the referenced predicate devices are specified for adult through neonatal patient types (based upon appropriate patient-applied accessories utilized for each parameter measurement). Application sites are equivalent and also based upon the selection of appropriate patient-applied accessories.
- The LifeWindow™ LW8 Lite Multi-Parameter Monitor and primary predicate device Biolight A Series Patient Monitor are specified for use in professional care environments. The EnviteC MySign O Oxygen Measuring Device is specified for hospital/professional, home, and (non-air) out transport environments. The Masimo Radical-7 Pulse CO-Oximeter is specified for professional and home environments. The claims of the LifeWindow™ LW8 Lite Multi-Parameter Monitor for professional use environments are within those of the referenced predicates.
- The LifeWindow™ LW8 Lite Multi-Parameter Monitor and predicate devices are prescription devices specified for professional use. As described above, the Masimo Radical-7 Pulse CO-Oximeter is additionally specified for home use.
- Like the predicate monitors, the LifeWindow™ LW8 Lite Multi-Parameter Monitor is a non-sterile device. Specific third-party patient-applied accessories such as invasive blood pressure transducers may be packaged/provided sterile by their respective manufacturers.
- Per the indications for use LifeWindow™ LW8 Lite Multi-Parameter Monitor claims a monitoring feature set equivalent to the Biolight A Series Patient Monitor for the following parameters:
    - ECG waveforms and heart rate from 3 or 5 lead (Biolight A Series includes 12 lead)
    - Non-invasive blood pressure (NIBP): systolic, diastolic, and mean arterial pressure
    - End-tidal CO2 concentration (EtCO2) - Mainstream or Sidestream

- Inspired CO2 concentration (insCO2) - Mainstream or Sidestream
- Fractional Inspired Oxygen (FiO2)
- Respiration Rate (from bioimpedance or EtCO2 measurement)
- Two Temperature channels
- Two Invasive Pressure channels (IP1, IP2)
- Pulse CO-Oximetry and pulse rate as previously described above

Summary points from specification comparisons:

- The LifeWindow™ LW8 Lite Multi-Parameter Monitor and the primary predicate device Biolight A Series Patient Monitor measure the same vital parameters and specify similar ranges for performance characteristics.
- Both the LifeWindow™ LW8 Lite Multi-Parameter Monitor and the primary predicate device Biolight A Series Patient Monitor offer the cleared Biolight electrocardiogram (ECG) measurement technology, which includes respiration rate by thoracic bioimpedance. ECG measurement principles and performance levels are equivalent, with some differences in waveform display.
- The LifeWindow™ LW8 Lite Monitor does not implement the EGC arrhythmia or ST segment functionality, the predicate device Biolight A Series Patient Monitor does. The LifeWindow™ LW8 Lite Monitor offers 3 lead and 5 lead ECG, the Biolight A Series Patient Monitor offers 3 lead, 5 lead, and 12 lead monitoring.
- Both the LifeWindow™ LW8 Lite Multi-Parameter Monitor and the primary predicate Biolight A Series Patient Monitor offer the cleared Masimo parameter measurement technology of multi-wavelength pulse co-oximetry, and offer similar third party Masimo sensor configurations (finger, disposable, etc.). Pulse co-oximetry measurement principles and performance levels are equivalent.
- The LifeWindow™ LW8 Lite Multi-Parameter Monitor and the predicate Masimo Radical-7 Monitor both offer acoustic respiration rate measurement (RRa) using cleared Masimo technology and third party sensors, the Biolight A Series Patient Monitor does not claim this feature.
- Both the LifeWindow™ LW8 Lite Multi-Parameter Monitor and the primary predicate Biolight A Series Patient Monitor offer the cleared Suntech non-invasive oscillometric (NIBP) parameter measurement technology. NIBP measurement principles and performance levels are equivalent.
- Both the LifeWindow™ LW8 Lite Multi-Parameter Monitor and the primary predicate Biolight A Series Patient Monitor offer the cleared Respironics sidestream and mainstream end tidal CO2 (EtCO2) parameter measurement technology. EtCO2 measurement principles and performance levels are equivalent.
- The LifeWindow™ LW8 Lite Multi-Parameter Monitor and the primary predicate Biolight A Series Patient Monitor both measure inspired Oxygen (FiO2). The measurement principles are different for the devices – the Biolight A Series Patient Monitor uses a paramagnetic Oxygen sensor and the LifeWindow™ LW8 Lite Monitor uses a cleared EnviteC electro-galvanic Oxygen cell. The measurement ranges are equivalent.
- The LifeWindow™ LW8 Lite Multi-Parameter Monitor and the primary predicate Biolight A Series Patient Monitor both offer the measurement of invasive blood pressure (IBP) parameter using cleared third party blood pressure transducers. Pressure measurement principles and performance levels are equivalent.

- The LifeWindow™ LW8 Lite Multi-Parameter Monitor and the primary predicate Biolight A Series Patient Monitor both offer the measurement of patient temperature parameter via cleared third party thermistor sensors meeting the YSI-400 temperature specification. Temperature measurement principles and performance levels are equivalent. The LifeWindow™ LW8 Lite Monitor offers two temperature monitoring channels, the Biolight A Series Patient Monitor offers up to eight channels by adding measurement modules.
- The LifeWindow™ LW8 Lite Multi-Parameter Monitor and the predicate Biolight A Series Patient Monitor both provide physiological alarms and have similar low and high level alarm settings and functions. Both monitors provide visual and audible alarms. Audible alarms may be suspended.
- The environmental conditions of the LifeWindow™ LW8 Lite Multi-Parameter Monitor and the primary predicate Biolight A Series Patient Monitors specify similar ranges. The EnviteC MySign® O Oxygen Measuring Device has been tested to meet non-air out of hospital transport requirements.
- The LifeWindow™ LW8 Lite Multi-Parameter Monitor and the predicate Biolight A Series Patient Monitor both specify third party patient-applied accessories. Third party patient-applied accessories specified for use with the LifeWindow™ LW8 Lite Monitor have been 510(k) cleared by their respective manufacturers.
- The LifeWindow™ LW8 Lite Multi-Parameter Monitor and the predicate Biolight A Series Patient Monitor both utilize color TFT LCD displays and have similar sizes (8.4 inch, 8.0 inch, respectively).
- The LifeWindow™ LW8 Lite Multi-Parameter Monitor and the predicate Biolight A Series Patient Monitor both offer key input and touch screen input with similar menu functionality.
- The LifeWindow™ LW8 Lite Multi-Parameter Monitor and the predicate Biolight A Series Patient Monitor both offer indicator LED's for the mains and battery charge status.
- The LifeWindow™ LW8 Lite Multi-Parameter Monitor and the predicate Biolight A Series Patient Monitor both offer an integrated thermal dot array printer with thermal paper width of 50 mm.
- The LifeWindow™ LW8 Lite Multi-Parameter Monitor and the predicate Biolight A Series Patient Monitor both may be connected to an external VGA display – the LifeWindow™ LW8 Lite Monitor specifies isolation components (i.e. isolation transformer) to be used when connecting to external components.
- The LifeWindow™ LW8 Lite Multi-Parameter Monitor and the predicate Biolight A Series Patient Monitor both offer USB and RJ45 network connector to support external printers. For a USB or RJ45 connected printer the LifeWindow™ LW8 Lite Monitor specifies isolation components (i.e. port isolators, transformer) to be used when connecting to external components.
- The LifeWindow™ LW8 Lite Multi-Parameter Monitor and the predicate Biolight A Series Patient Monitor both have similar mains power requirements including a universal power supply input range of 100-240 VAC, 50/60Hz.
- The LifeWindow™ LW8 Lite Multi-Parameter Monitor incorporates an internal rechargeable sealed lead-acid battery and the predicate Biolight A Series Patient Monitor utilizes an internal Li-Ion battery source – the functionality of the batteries is the same, operation when disconnected from mains.
- The physical size and weight of the LifeWindow™ LW8 Lite Multi-Parameter Monitor and the predicate Biolight A Series Patient Monitors are similar – the

LifeWindow™ LW8 Lite Multi-Parameter Monitor is slightly smaller in size at 235 x 175 x 165 mm, and at 4.5kg it weighs slightly more compared to 4.2 kg for the predicate Biolight Monitor.

In conclusion, the LifeWindow™ LW8 Lite Multi-Parameter Monitor is equivalent in its intended use to the predicate devices, the Biolight A Series and Q Series Patient Monitors, EnviteC MySign® O Oxygen Measuring Device, and Masimo Radical-7 Pulse CO-Oximeter.

In summary, the LifeWindow™ LW8 Lite Multi-Parameter Monitor utilizes equivalent technology and has similar technical specifications as the predicate devices and the reference devices, the Biolight A Series and Q Series Patient Monitors, EnviteC MySign® O Oxygen Measuring Device, and Masimo Radical-7 Pulse CO-Oximeter, respectively. The claims of the subject device are within those of the predicate and reference devices.

Therefore, in consideration of the above, the technological characteristics of the devices do not raise different questions of safety and effectiveness when used as labeled and do not impact the Intended Use of the device for use as a multi-parameter monitor.

(b) (1) **Non-Clinical Tests Submitted:**

LifeWindow™ LW8 Lite Multi-Parameter Monitor was laboratory tested to current applicable standards for medical device electrical safety and electromagnetic compatibility as well as particular standards for multi-function patient monitors. The following standards were utilized in compliance testing:

- Electrical safety testing per IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012) or IEC 60601-1: 2012 (FDA recognition number 19-4)
- Electromagnetic compatibility testing per IEC 60601-1-2:2007, 3rd Edition (FDA recognition number 19-1)
- Usability evaluation per IEC 60601-1-6:2010 (FDA recognition number 5-89) and IEC 62366:2007 (FDA recognition number 5-114) for professional use
- Medical alarm systems testing per IEC 60601-1-8:2006+A1:2012 (FDA recognition number 5-76)
- Particular requirements for Electrocardiographic monitors per IEC 60601-2-27:2011, 3rd Edition (FDA recognition number 3-126)
- Particular requirements for automated non-invasive sphygmomanometers per IEC 80601-2-30:2013, Edition 1.1 (FDA recognition number 3-152)
- Particular requirements for invasive blood pressure monitors per IEC 60601-2-34:2011, 3rd Edition (FDA recognition number 3-115)
- Particular requirements for multifunction patient monitors per IEC 60601-2-49:2011 (FDA recognition number (none))
- Particular requirements for respiratory gas monitors per ISO 80601-2-55:2011, 1st Edition (FDA recognition number 1-96)
- Particular requirements for clinical thermometers per ISO 80601-2-56:2009 (FDA recognition number 6-403)
- Particular requirements for pulse oximeter equipment per ISO 80601-2-61:2011, 1st Edition (FDA recognition number 1-85)

- Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure To Radio Frequency Identification Readers, AIM Standard 7351731:2016, Rev. 1 (FDA recognition number 19-21)

The monitor met the acceptance criteria for compliance to the standards.

The monitor was evaluated to the requirements of the following guidance documents:

- Cardiac Monitor Guidance (including Cardiotachometer and Rate Alarm), Issued November 5, 1998
- FDA Non-invasive Blood Pressure (NIBP) Guidance Document, March 10, 1997
- Guidance on the Content of Premarket Notification [510(k)] Submissions for Clinical Electronic Thermometers, March 1993
- Pulse Oximeters – Premarket Notification Submissions [510(k)s] Guidance for Industry and Food and Drug Administration Staff March 4, 2013
- Applying Human Factors and Usability Engineering To Medical Devices - Guidance For Industry And Food And Drug Administration Staff, Feb 3, 2016

The monitor met the requirements and/or recommendations of the guidance documents.

Risk management, risk and hazard analysis of the probes was performed to the following standard:

- Application of risk management to medical devices per ISO 14971

The monitor met acceptance criteria for residual risks.

The LifeWindow™ LW8 Lite Multi-Parameter Monitor software was developed in accordance with FDA guidelines for MAJOR level of concern devices. The software lifecycle process was evaluated to meet:

- Medical device software – Software life-cycle processes per IEC 62304:2006 (First Edition) + A1:2015 (FDA recognition number 13-79)
- Medical device software lifecycle process per IEC 62304 with software safety class C (equivalent to MAJOR level of concern).
- FDA Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, October 2, 2014.

The device software was verified to requirements and validated to meet the specified intended use(s).

A usability / Human Factors/Usability summative study was conducted on the LifeWindow™ LW8 Lite Multi-Parameter Monitor with 15 representative professional users (USA) in a simulated critical care scenario with vital signs generation on the subject software. The study followed the FDA usability guidance. The subject device has been found to be safe and effective for the intended users, uses and use environments.

In summary, the LifeWindow™ LW8 Lite Multi-Parameter Monitor met test criteria for standards conformance to the applicable standards and guidance documents, and residual risks met criteria for acceptability for the intended use.

(2) Clinical Tests Submitted:

(none)

(3) Conclusions from Tests:

As described in (b)(1) and (b)(2) above, the LifeWindow™ LW8 Lite Multi-Parameter Monitor is equivalent to the predicate devices as supported by compliance, laboratory, and biocompatibility testing.

The results of all tests demonstrate that the LifeWindow™ LW8 Lite Multi-Parameter Monitor meet specified requirements and criteria for substantial equivalence to the referenced predicate devices.