August 20, 2026

Draeger Medical Systems, Inc.
Melissa Gray
Senior Manager Regulatory Affairs
6 Tech Dr.
Andover, Massachusetts 01810

Re: K260579
Trade/Device Name: Infinity® Acute Care System (IACS) - VG8.1
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector And Alarm (Including ST-Segment Measurement And Alarm)
Regulatory Class: Class II
Product Code: MHX, MSX, DRT, DQA, DSK, MLD, DXN, DSF, DSA, DSB, DQE, DXG, BZQ, CCK, FLL, DSI, DPS
Dated: July 23, 2026
Received: July 24, 2026

Dear Melissa Gray:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the 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 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260579

Please provide the device trade name(s).

Infinity Acute Care System (IACS)

Please provide your Indications for Use below.

Infinity Acute Care System (IACS)

Intended Use
The IACS is intended for multi-parameter, physiologic patient monitoring of adult, pediatric, and neonatal patients in environments where patient care is provided by trained health care professionals.

The IACS obtains the physiologic, multi-parameter data from the connection to the M540 monitor and optional medical devices and displays. The real-time physiologic and multi-parameter data collected from the IACS is made available on the Infinity Network.

Environments of Use
The device is intended for environments where patient care is provided by trained healthcare professionals, but not in the following environments:
– Homecare use
– Hyperbaric chambers
– Environments containing MRI equipment
– Areas where Oxygen concentrations above 25 Vol % for combustible or explosive gas mixtures can occur

Indications for use
The IACS, in connection with the M540 Patient Monitor, monitors the following parameters:
– Heart rate
– Arrhythmia (adult and pediatric patients only)
– 12-lead Rest ECG analysis (adult and pediatric patients only)
– ST segment analysis including TruST (adult and pediatric patients only)
– Impedance respiratory rate – (RRi)
– Invasive blood pressure – (IBP)
– Non-invasive blood pressure – (NIBP)
– Temperature
– Cardiac output (adult and pediatric patients only)
– Carbon dioxide – (etCO2, inCO2, RRc)
– Non-invasive arterial oxygen saturation – (SpO2)
  • Pulse rate
  • Perfusion index – (PI)
  • Total hemoglobin – (SpHb) (adult and pediatric patients only)
  • Total oxygen content – (SpOC) (adult and pediatric patients only)
  • Carboxyhemoglobin saturation – (SpCO) (adult and pediatric patients only)
  • Methemoglobin saturation – (SpMet)
  • Pleth variability index – (PVI)

The IACS is also capable of connecting to third-party devices to display physiologic, multi-parameter data,

store trends and send data across the Infinity network.

Infinity Medical Cockpits

Intended Use
The Infinity Medical Cockpits, consisting of the C500, and the C700 are monitoring and control displays for the Infinity Acute Care System (IACS).

Medical Cockpits are intended to be used to monitor waveforms, parameter information, and alarms and to control settings.

The Infinity Series Medical Cockpits are intended to be used in environments where patient care is provided by trained healthcare professionals.

Environments of Use
The Infinity Series Medical Cockpits are intended for use in environments where patient care is provided by trained healthcare professionals, but not in the following environments:
– Homecare use
– Hyperbaric chambers
– Environments containing MRI equipment
– Areas where Oxygen concentrations above 25 Vol % for combustible or explosive gas mixtures can occur

Indications for Use
As the Infinity Medical Cockpits are used in conjunction with the Infinity Acute Care System and the M540 Patient Monitors they do not have their own indication for use.

Infinity M540

Intended Use
The Infinity M540 (M540) is intended for multi-parameter, physiologic patient monitoring of adult, pediatric, and neonatal patient information in environments where patient care is provided by trained health care professionals.

The M540 obtains physiological data from connection to optional accessory devices. The real-time physiologic and multi-parameter data collected from the M540 is made available on the Infinity network.

The M540 is intended to monitor one patient at a time.

Environments of Use
The device is intended for environments where patient care is provided by trained healthcare professionals, but not in the following environments:
– Homecare use
– Hyperbaric chambers
– Environments containing MRI equipment
– Areas where oxygen concentrations above 25 Vol % or combustible or explosive gas mixtures can occur

Indications for use
The M540 monitors the following parameters:
– Heart rate
– Arrhythmia (adult and pediatric patients only)
– 12-lead Rest ECG analysis (adult and pediatric patients only)
– ST segment analysis including TruST (adult and pediatric patients only)

– Impedance respiratory rate – (RRi)
– Invasive blood pressure – (IBP)
– Non-invasive blood pressure – (NIBP)
– Temperature
– Cardiac output – only available when the M540 is docked in an IACS configuration (adult and pediatric patients only)
– Carbon dioxide – (etCO2, inCO2, RRc)
– Non-invasive arterial oxygen saturation – (SpO2)
  • Pulse rate
  • Perfusion index – (PI)
  • Total hemoglobin – (SpHb) (adult and pediatric patients only)
  • Total oxygen content – (SpOC) (adult and pediatric patients only)
  • Carboxyhemoglobin saturation – (SpCO) (adult and pediatric patients only)
  • Methemoglobin saturation – (SpMet)
  • Pleth variability index – (PVI)

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)	?

510(k) Summary

1 Submitter

Date Prepared	July 23, 2026
Submitter/Owner	Draeger Medical Systems, Inc. 6 Tech Drive Andover, MA 01810-2434 Tel: (978) 447-3613
Key Contact	Melissa Gray Senior Manager Regulatory Affairs Melissa.Gray@draeger.com
510(k) Submission Type	Traditional 510(k)

2 Device

Trade Name	Infinity® Acute Care System (IACS) – VG8.1
Common Name	Multi-parameter patient monitor
Classification Name	Monitor, Physiological, Patient (with Arrhythmia detection or alarms) Regulation Number: 21 CFR §870.1025 Regulatory Class: II Primary Product Code: MHX Associated Product Codes: MSX, DRT, DQA, DSK, MLD, DXN, DSF, DSA, DSB, DQE, DXG, BZQ, CCK, FLL, DSI, DPS

3 Predicate Device

Predicate Device	**510(k) No.**	**Company**	**Device Name**	**Product Codes**
	K203088	Draeger Medical Systems, Inc.	Infinity Acute Care System (IACS) – VG4.2	MHX, MSX, DRT, DQA, DSK, MLD, DXN, DSF, DSA, DSB, DQE, DXG, BZQ, FLS, CCK, FLL, DSI, DPS

The subject device is substantially equivalent to the legally marketed predicate device.

4 Device Description

Infinity Acute Care System (IACS), VG8.1 – description of the device per 21 CFR 807.92(a)(4)

The Infinity Acute Care System (IACS) is a multi-parameter physiological patient monitoring system that acquires and displays patient data at the bedside. The IACS is comprised of the following devices: the Infinity M540 Patient Monitor with the Infinity M500 Docking Station, integrated with the Infinity Medical Cockpit and respective software, powered by the Infinity P2500 power supply.

The physiological patient data acquired from the interconnected components is displayed on the Infinity M540 Patient Monitor and is transmitted via network to the patient bedside Infinity Medical Cockpit. The Infinity M540 Patient Monitor is a lightweight, hand-held, portable patient monitor that displays real-time vital signs, provides continuous trending, and produces visual and audible alarms if any of the physiological parameters monitored vary beyond preset limits, and transmits the data over the network. The Infinity M540 Patient Monitor can be used as a stand-alone medical device without any integration with the Infinity Medical Cockpits.

5 Intended Use and Indications for Use	
Intended Use as required per 21 CFR 807.92(a)(5)	
Intended Use / Environments of Use — IACS	The IACS is intended for multi-parameter, physiologic patient monitoring of adult, pediatric, and neonatal patients in environments where patient care is provided by trained health care professionals. The IACS obtains the physiologic, multi-parameter data from the connection to the M540 monitor and optional medical devices and displays. The real-time physiologic and multi-parameter data collected from the IACS is made available on the Infinity Network. Environments of Use — The device is intended for environments where patient care is provided by trained healthcare professionals, but not in the following environments: - Home care - Hyperbaric chambers - Environments containing MRI equipment - Areas where oxygen concentrations above 25 Vol% or combustible or explosive gas mixtures can occur
Intended Use / Environments of Use — Infinity M540 Patient Monitor	The Infinity M540 (M540) is intended for multi-parameter, physiologic patient monitoring of adult, pediatric, and neonatal patient information in environments where patient care is provided by trained health care professionals. The M540 obtains physiological data from connection to optional accessory devices. The real-time physiologic and multi-parameter data collected from the M540 is made available on the Infinity network. The M540 is intended to monitor one patient at a time. Environments of Use — The device is intended for environments where patient care is provided by trained healthcare professionals, but not in the following environments: - Homecare use - Hyperbaric chambers - Environments containing MRI equipment - Areas where oxygen concentrations above 25 Vol% or combustible or explosive gas mixtures can occur
Intended Use / Environments of Use — Medical Cockpits	The Infinity Medical Cockpits, consisting of the C500 and the C700, are monitoring and control displays for the Infinity Acute Care System (IACS). Medical Cockpits are intended to be used to monitor waveforms, parameter information, and alarms, and to control settings. The Infinity Series Medical Cockpits are intended to be used in environments where patient care is provided by trained healthcare professionals. Environments of Use — The Infinity Series Medical Cockpits are intended for use in healthcare environments only where patient care is provided by trained healthcare professionals, but not in the following environments: - Homecare use - Hyperbaric chambers - Environments containing MRI equipment - Areas where oxygen concentrations above 25 Vol% for combustible or explosive gas mixtures can occur

Indications for Use — IACS	The IACS, in connection with the M540 Patient Monitor, monitors the following parameters:
	- Heart rate
	- Arrhythmia (adult and pediatric patients only)
	- 12-lead Rest ECG analysis (adult and pediatric patients only)
	- ST segment analysis including TruST (adult and pediatric patients only)
	- Impedance respiratory rate (RRi)
	- Invasive blood pressure (IBP)
	- Non-invasive blood pressure (NIBP)
	- Temperature
	- Cardiac output (adult and pediatric patients only)
	- Carbon dioxide (etCO2, inCO2, RRc)
	- Non-invasive arterial oxygen saturation (SpO2) including:
	  ○ Pulse rate
	  ○ Perfusion index (PI)
	  ○ Total hemoglobin (SpHb) (adult and pediatric patients only)
	  ○ Total oxygen content (SpOC) (adult and pediatric patients only)
	  ○ Carboxyhemoglobin saturation (SpCO) (adult and pediatric patients only)
	  ○ Methemoglobin saturation (SpMet)
	  ○ Pleth variability index (PVI)
	The IACS is also capable of connecting to third-party devices to display physiologic, multi-parameter data, store trends, and send data across a network.

Indications for Use — Infinity M540 Patient Monitor	The M540 monitors the following parameters:
	- Heart rate
	- Arrhythmia (adult and pediatric patients only)
	- 12-lead Rest ECG analysis (adult and pediatric patients only)
	- ST segment analysis including TruST (adult and pediatric patients only)
	- Impedance respiratory rate (RRi)
	- Invasive blood pressure (IBP)
	- Non-invasive blood pressure (NIBP)
	- Temperature
	- Cardiac output – only available when the M540 is docked in an IACS configuration (adult and pediatric patients only)
	- Carbon dioxide (etCO2, inCO2, RRc)
	- Non-invasive arterial oxygen saturation (SpO2) including:
	  ○ Pulse rate
	  ○ Perfusion index (PI)
	  ○ Total hemoglobin (SpHb) (adult and pediatric patients only)
	  ○ Total oxygen content (SpOC) (adult and pediatric patients only)
	  ○ Carboxyhemoglobin saturation (SpCO) (adult and pediatric patients only)
	  ○ Methemoglobin saturation (SpMet)
	  ○ Pleth variability index (PVI)

5.1 Comparison of Intended Use and Indications for Use

The Intended Use and Indications for Use of the Subject VG8.1 IACS, Infinity M540 Patient Monitor, and Medical Cockpits are substantially the same as those of the predicate IACS VG4.2. Most changes are labeling clarifications with no impact on scope: the Environment of Use statement now explicitly excludes home care and oxygen-rich/combustible atmospheres, redundant "for the monitoring" wording was removed from the M540 statement, and "Non-invasive" was added to the arterial oxygen saturation indication to more precisely describe the existing measurement method.

The Apnea indication and its associated product code "FLS" were removed from the VG8.1 labeling, narrowing the Indications for Use. The term "apnea" remains elsewhere in the IFU for terminology alignment with recently cleared devices, though it is no longer a labeled indication.

The subject device's Intended Use and Indications for Use are substantially equivalent to the predicate.

6 Comparison of Technological Characteristics with Predicate Device

Item of Comparison	Description/Rationale	Same/Similar/New
Legal Manufacturer	Draeger Medical Systems, Inc. — Identical to predicate.	**Same**
FDA Classification	21 CFR §870.1025 – Cardiovascular – Identical to predicate.	**Same**
FDA Product Code (Primary)	MHX – Identical to predicate.	**Same**
FDA Product Code (Associated)	Associated product code FLS (apnea monitor, facility use) has been removed in VG8.1. All other associated product codes remain the same.	**Similar**
M540 Patient Monitor – New Variant MS40636	VG8.1 adds a new M540 variant, MS40636, with a new wireless radio (compliant with IEEE 802.11b/g/n WLAN standards) and new outer-case materials (straight-edged design; white front shell, gray back housing; hard case, no over-mold; raised buttons). Performance and functionality remain unchanged. The M540 IFU reprocessing section was updated based on testing performed for this submission.	**Similar**
Medical Cockpit – Gen 3	VG8.1 adds a new Medical Cockpit. The Gen 3 Medical Cockpit includes an updated CPU, a slightly larger display, the addition of Display Ports (DP) and USB 3.0 ports, and more RAM memory and disk storage.	**Similar**
WIFI (M540)	Similar to predicate; no changes to functionality.	**Similar**
Intended Use / Environments of Use (IACS, M540, Medical Cockpits)	Similar to predicate. Added environment-of-use restrictions (home care; oxygen-rich/combustible atmospheres) are clarifications only and do not change the Intended Use or Indications for Use.	**Similar**
Indications for Use (IACS, M540)	Similar to predicate. Removal of the Apnea indication and addition of “Non-invasive” to the SpO2 indication have no impact on Intended Use or Indications for Use relative to supporting data.	**Similar**
Cybersecurity Enhancements	Enhancements to packet storm mitigation Data-in-transit, Password security	**New**
Operating System	VG8.1 uses a hardened Windows 10 IoT Enterprise LTSC, versus Windows XP Embedded in the predicate.	**Similar**
Patching / Hotfixes	VG8.1 supports Windows 10 and Edge patches/hotfixes	**New**
SpO2 Alarms	VG8.1 makes the desaturation alarm always enabled (ON) for all patient populations and adds new low-priority advisory alarm messages for SpO2 sensor/cable status (predicate: desaturation alarm conditional, neonates only). Configurable SpO2 sensor-off/check-sensor alarm priority is unchanged; the changes are informational and do not affect core SpO2 measurement performance.	**Similar**

Dual SpO2 Monitoring	VG8.1 introduces dual SpO2 monitoring via a secondary SpO2 source connected to the Cockpit through an RS-232 interface (not supported in predicate). The IACS acts as a display-only interface for the secondary data and does not generate or annunciate alarms for the external SpO2 device.	**New**
M540 Respiration Monitoring	VG8.1 removes Manual Mode (Auto Mode unchanged). Detection threshold, measurement range, and resolution for Auto Mode are identical to predicate. Respiration accuracy presentation was revised from a mixed bpm/% format to a bpm-only format	**Similar**
CO2 Monitoring – Mainstream Compatibility	VG8.1 remains compatible with MCable Mainstream CO2 variant 6871950 (K100941) and introduces compatibility with the Infinity MCable Mainstream CO2 variant 6873570 (K221118), due to future obsolescence of the 6871950 variant.	**Similar**
CO2 Monitoring – Infinity MCable Mainstream CO2 variant (6871950)	The IACS makes no modification to this sensor. It displays the measurement output without analysis or modification, with identical claims (intended use, indications, intended population, environment of use) to the cleared sensor (K100941). The IACS compatibility with this sensor remains the same as with the predicate (IACS VG4.2, K203088).	**Same**
CO2 Monitoring – Infinity MCable Mainstream CO2 variant (6873570)	The IACS makes no modification to this sensor. It displays the measurement output without analysis or modification, with identical claims (intended use, indications, intended population, environment of use) to the cleared sensor (K221118).	**New**
CO2 Monitoring – Infinity MCable Microstream Compatibility	New in VG8.1: compatibility with the Infinity MCable Microstream CO2 (Oridion device without Draeger branding, cleared under K094012) for intubated and non-intubated patients, adults, pediatrics, and neonates.	**New**
CO2 MCable Respiratory – Measuring Method/ Range/Accuracy (Mainstream variants)	Measuring method, range, and accuracy identical to predicate for both mainstream CO2 variants.	**Same**
CO2 MCable Respiratory – Measuring Method/Range (Microstream)	New measuring method introduced with the Microstream accessory: sidestream infrared absorption spectroscopy; measuring range (etCO2/inCO2) 0–99 mmHg; respiratory rate range 0–150 bpm; respiratory rate accuracy +/-1 bpm (0–70 bpm), +/-2 bpm (71–120 bpm), +/-3 bpm (121–150 bpm). Uses the same measuring method and range as the Medtronic MicroMediCO2 module.	**New**
Parameter Display – Mainstream CO2 variants	Parameters (etCO2, inCO2, RRc) identical to predicate.	**Same**
Parameter Display – Microstream CO2	New parameters displayed via Microstream accessory: etCO2, inCO2, RRc — same parameters as the Medtronic MicroMediCO2 module.	**New**

Reprocessing	Reprocessing information updated for the M540 and M500 Docking Station, including IFU formatting changes and updated disinfectant information, since predicate clearance (K203088).	**Similar**
Biocompatibility	Unaffected by the changes, same as predicate.	**Same**
Sterility / Shelf-Life	Unaffected by the changes, same as predicate.	**Same**
Substantial Equivalence Summary		
Operational and technological characteristics form the basis for the determination of substantial equivalence of the subject device with the legally marketed predicate device (K203088). The proposed modifications do not change the fundamental scientific technology of the cleared device. The subject device is substantially equivalent to the predicate device.		
7 Performance Data		
Verification Testing	Draeger evaluated the substantial equivalence of the device with proposed modifications through system performance and verification testing. Draeger performed a risk assessment for the devices with proposed modifications and identified the need for risk mitigations to support cybersecurity protections. The risk control measures were designed, developed, and tested in accordance with 21 CFR 820.30 design controls. The results of verification testing confirm that the modified device continues to meet equivalent criteria demonstrating substantial equivalence to the predicate device. The device with proposed modifications meets the criteria for substantial equivalence to the predicate device.	
Validation Testing	Draeger design controls in compliance with 21 CFR 820.30(g) govern validation and risk analysis of device modifications. Draeger identified hazardous situations following recommendations in FDA guidance documents “General Principles of Software Validation” (issued January 2002) and “Applying Human Factors and Usability Engineering to Medical Devices” (issued February 2016). Validation tests were conducted to confirm the implementation of software design input requirements, established risk mitigations, and user adoption of the proposed modifications. Validation test results support the claim of substantial equivalence to the predicate device.	
Biocompatibility	The Infinity Acute Care System (IACS) VG8.1, like its predicate Infinity Acute Care System, Monitoring Solution VG4.2, has no patient contact. Any contact with the Infinity M540 Patient Monitor is transient with intact skin. The IACS was not impacted by the proposed changes, therefore, biocompatibility is not applicable.	
Reprocessing	The reprocessing information for the subject device, Infinity Acute Care System (IACS) VG8.1 has been updated for the Infinity M540 Patient Monitor and the Infinity M500 Docking Station since the predicate device, Infinity Acute Care System, Monitoring Solution VG4.2, was cleared via K203088 on February 1, 2022. In addition to formatting changes in the IFUs for the reprocessing information, updated disinfectant information for the M540 and M500 devices is included.	
Sterility and Shelf-Life	Infinity Acute Care System (IACS) VG8.1, like its predicate Infinity Acute Care System, Monitoring Solution VG4.2, is Capital Equipment and does not require sterilization to accomplish its intended use and is supplied and used non-sterile. Therefore, sterilization data and shelf-life data are not applicable.	

Non-Clinical Tests – Harmonized Standards		
The subject device includes hardware changes since the predicate was cleared via K203088. It was tested and complies with the following recognized standards:		
Standard	**Edition/ Year**	**Title**
AAMI EC57	2012	Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms
ISO 15223-1	2021	Medical devices – symbols to be used with information to be supplied by the manufacturer
IEC 62304	2015, Edition 1.1	Medical device software – Software life cycle process
ANSI/AAMI 60601-1	2005 & A1:2012 & A2:2021	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2	2014 + A1:2020, Edition 4.1	Medical electrical equipment – Part 1-2: Collateral Standard: Electromagnetic disturbances – Requirements and tests
IEC 60601-1-6	2010 + A1:2013 + A2:2020	Medical electrical equipment – Part 1-6: Collateral standard: Usability
IEC 62366-1	2015 + A1:2020	Medical devices – Application of usability engineering to medical devices
ISO 14971	2019	Medical devices – Application of risk management to medical devices
IEC 60601-1-8	2006 + AMD1:2012 + AMD2:2020 (Ed 2.2)	Medical electrical equipment – Part 1-8: Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 60601-2-25	2011	Medical electrical equipment – Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
IEC 60601-2-27	2011 (COR 1 2012)	Medical electrical equipment – Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
IEC 60601-2-34	2011	Medical electrical equipment – Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment
ISO 80601-2-30	2018	Medical electrical equipment – Part 2-30: Particular requirements for automated non-invasive sphygmomanometers
ISO 80601-2-49	2018	Medical electrical equipment – Part 2-49: Particular requirements for multifunction patient monitors
ISO 80601-2-55	2018	Medical electrical equipment – Part 2-55: Particular requirements for respiratory gas monitors

ISO 80601-2-56	2017, AMD1:2018	Medical electrical equipment – Part 2-56: Particular requirements for clinical thermometers for body temperature measurement
ISO 80601-2-61	2017 (Corrected version 2018-02)	Medical electrical equipment – Part 2-61: Particular requirements for pulse oximeter equipment
IEC 81001-5-1	2021	Health software and health IT systems safety, effectiveness and security - Part 5-1: Security - Activities in the product life cycle
ISO 17664-2	2021	Processing of health care products – Information to be provided by the medical device manufacturer, Part 2: Non-critical medical devices
Non-clinical Bench Tests	No new issues of substantial equivalence are introduced by the changes proposed for the IACS VG8.1 compared to the predicate. Verification and validation testing (see above) support the claim of substantial equivalence.	
Clinical Studies	Substantial equivalence was supported through non-clinical verification and validation testing.	

8 Conclusion

The Infinity Acute Care System (IACS) VG8.1 subject device is substantially equivalent to the predicate device Infinity Acute Care System, Monitoring Solution VG4.2 (cleared via K203088, February 1, 2022).

This conclusion is supported by non-clinical bench testing, electrical safety and electromagnetic compatibility assessments, and verification and validation. Together, these results confirm that the modified device does not raise different questions of safety or effectiveness compared to the predicate, performs as intended, and has performance characteristics and intended use substantially equivalent to the predicate device.