April 10, 2026

Shanghai Draeger Medical Instrument Co., Ltd.
Xuguang Miao
Senior Regulatory Affairs Specialist
229 Hupo Rd., Shanghai International Medical Zone Pudong New Area
Shanghai, Shanghai 201321 CHN

Re: K252250
Trade/Device Name: Vista 300/Vista 300 S; Vista 300 Non-Inv Model A, US (2601064); Vista 300 Invasive Model C, US (2601065); Vista 300 S Non-Inv Model A, US (2602425); Vista 300 S Invasive Model B, US (2602426); Vista 300 S Invasive Model C, US (2602427)
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, DPS, DSI, MLD, DRT, DXN, DSK, FLL, DQA, BZQ, CCK, KOI, OLT, OLW, OMC, ORT
Dated: July 17, 2025
Received: July 17, 2025

Dear Xuguang Miao:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252250

Device Name
Vista 300/Vista 300 S

Indications for Use *(Describe)*

Vista 300:
The monitors are intended to be used for monitoring, storing, recording and reviewing of, and to generate alarms for, multiple physiological parameters of adults, pediatrics and neonates. The monitors are intended for use by trained healthcare professionals in hospital environments.
The monitored physiological parameters include: ECG, respiration (RESP), temperature (TEMP), oxygen saturation of arterial blood (SpO_2), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), carbon dioxide (CO_2), cardiac output (C.O.), anesthetic Gas (AG), bispectral index (BIS), neuromuscular transmission (NMT).
The monitors are not intended for MRI environments.

Vista 300 S:
The monitors are intended to be used for monitoring, storing, recording and reviewing of, and to generate alarms for, multiple physiological parameters of adults, pediatrics and neonates. The monitors are intended for use by trained healthcare professionals in hospital environments.
The monitored physiological parameters include: ECG, respiration (RESP), temperature (TEMP), oxygen saturation of arterial blood (SpO_2), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), carbon dioxide (CO_2), cardiac output (C.O.) (for adults only), anesthetic Gas (AG).
The monitors are not intended for MRI environments.

For Vista 300/Vista 300 S:
The arrhythmia detection and ST Segment analysis are intended for adult patients.
The NIBP monitoring supports iCUFS algorithm. The iCUFS algorithm is intended for adult, pediatric and neonatal patients. It is also intended for use with pregnant women, including pre-eclamptic patients. NIBP MAP is not applicable to pregnant women.

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.

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510(k) Premarket Notification Summary

Submitter:

Shanghai Draeger Medical Instrument Co., Ltd.
3#, No.229, Hupo Road
Shanghai International Medical Zone
201321, Shanghai, China
Establishment's registration number: 3019545235

Contact Person:

Xuguang Miao

Associate Regulatory Manager
E-Mail: xuguang.miao@draeger.com
Telephone: +86 021 3108 6000

US Agent:

Name: Melissa Gray
Sr Mgr Regulatory Affairs
Address: Draeger Medical Systems, Inc.
6 Tech Dr
Andover, Massachusetts, 01810, USA
E-mail: melissa.gray@draeger.com
Telephone: +1 978-447-3613

Date Prepared: 10 April 2026

Device Name:

Trade name:	Vista 300/Vista 300 S
Common name:	Vista 300/Vista 300 S
Regulation number:	21 CFR § 870.1025
Classification name:	Monitor, Physiological, Patient (With Arrhythmia Detection Or Alarms)
Class:	II
Primary product code:	MHX

Associated Product codes:

Regulation number/ Device	Code
21 CFR 868.2375 Electrocardiograph	DPS
21 CFR 870.2340 Detector and alarm, arrhythmia	DSI
21 CFR 870.1025 Monitor, St segment with alarm	MLD

21 CFR 870.2300 Monitor, cardiac (incl. cardiotachometer & rate alarm)	DRT
21 CFR 870.1130 System, measurement, blood-pressure, non-invasive	DXN
21 CFR 870.1110 Computer, blood-pressure	DSK
21 CFR 880.2910 Thermometer, electronic, clinical	FLL
21 CFR 870.2700 Oximeter	DQA
21 CFR 868.2375 Monitor, Breathing Frequency	BZQ
21 CFR 870.1400 Analyzer, gas, carbon-dioxide, gaseous-phase	CCK
21 CFR 868.2775 Stimulator, nerve, peripheral, electric	KOI
21 CFR 882.1400 Non-normalizing quantitative electroencephalograph software	OLT
21 CFR 882.1400 Index-generating electroencephalograph software	OLW
21 CFR 882.1400 Reduced- montage standard electroencephalograph	OMC
21 CFR 882.1400 Burst suppression detection software for electroencephalograph	ORT

Predicate Device: Patient Monitor, Model: iX10, iX12, iX15, K232962

Reference Devices: Dräger Infinity Acute Care System (IACS) Monitoring System, K203088

Dräger CO2 Mainstream Sensor, K221118

Oridion Medical 1987 Capnostream 35 Portable

Respiratory Monitor, K150272

Covidien Microstream CO2 NanoPod, K213911

ASPECT BISx, K040183 and BISx4, K052981

IDMED ToFscan, K172690

Device Description

The Vista 300 and Vista 300 S are bed-side, multi-parameter physiological patient monitors intended to provide continuous, real-time monitoring of vital signs in adult, pediatric, and neonatal patients. Each monitor is equipped with a high-resolution color touchscreen display (15.6 inches for Vista 300; 13.3 inches for Vista 300 S) and a set of dedicated hardware buttons to facilitate user input and device navigation. The monitors are intended to be used in environments where patient care is provided by trained health care professionals, but not in the following environments: helicopter, transport, hospital ambulance, or home use.

The monitors are equipped with multiple connection ports to support the use of compatible accessories for the measurement of physiological parameters, including but not limited to electrocardiogram (ECG), blood oxygen saturation (SpO_2), non-invasive and invasive blood pressure, temperature, respiration rate, and carbon dioxide (CO_2), as applicable. Optional modules may be integrated to expand the functional capabilities.

The Vista 300 and Vista 300 S are software-driven devices. The system software processes raw physiological signals acquired from the patient through compatible accessories by applying signal filtering and measurement algorithms, or incorporates received processed data, and converts this information into clear, clinically relevant numerical and graphical displays. This information is presented on the color touchscreen display to support timely clinical assessment and decision-making. User input can be performed via the touchscreen or dedicated physical keys. Integrated alarm functions provide both visual and audible alerts in response to physiological parameters or device conditions that fall outside user-defined limits or require operator attention.

Patient data collected by the monitors may be stored locally to enable trend analysis and review, and may also be transmitted via network interfaces for integration with hospital information systems or central monitoring stations.

Intended Use/ Indications for Use

Vista 300:

The monitors are intended to be used for monitoring, storing, recording and reviewing of, and to generate alarms for, multiple physiological parameters of adults, pediatrics and neonates. The monitors are intended for use by trained healthcare professionals in hospital environments.

The monitored physiological parameters include: ECG, respiration (RESP), temperature (TEMP), oxygen saturation of arterial blood (SpO_2), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), carbon dioxide (CO_2), cardiac output (C.O.), anesthetic Gas (AG), bispectral index(BIS), neuromuscular transmission (NMT).

The monitors are not intended for MRI environments.

Vista 300 S:

The monitors are intended to be used for monitoring, storing, recording and reviewing of, and to generate alarms for, multiple physiological parameters of adults, pediatrics and neonates. The monitors are intended for use by trained healthcare professionals in hospital environments.

The monitored physiological parameters include: ECG, respiration (RESP), temperature (TEMP), oxygen saturation of arterial blood (SpO_2), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), carbon dioxide (CO_2), cardiac output (C.O.) (for adults only), anesthetic Gas (AG).

The monitors are not intended for MRI environments.

For Vista 300/Vista 300 S:

The arrhythmia detection and ST Segment analysis are intended for adult patients.

The NIBP monitoring supports iCUFS algorithm. The iCUFS algorithm is intended for adult, pediatric and neonatal patients. It is also intended for use with pregnant women, including pre-eclamptic patients. NIBP MAP is not applicable to pregnant women.

List of Recognized Consensus Standards

Standard Number and Version	Title
IEC 60601-1:2005+AMD1:2012+AMD2:2020	Medical electrical equipment Part 1: General requirements for basic safety and essential performance Incorporating corrigendum
IEC 60601-1-2:2014+AMD1:2020	Medical electrical equipment. General requirements for basic safety and essential performance. Collateral Standard. Electromagnetic disturbances. Requirements and tests
IEC 60601-1-8:2006+AMD2:2020	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 60601-2-10: 2012+AMD1:2016	Medical Electrical Equipment-Part 2: Particular Requirements For The Basic Safety And Essential Performance Of Nerve And Muscle Stimulators
IEC 60601-2-25:2011	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
IEC 80601-2-26:2019/AMD1:2024	Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs
IEC 60601-2-27:2011	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
IEC 80601-2-30:2018	Medical electrical equipment. Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
IEC 60601-2-34:2024	Medical electrical equipment - Part 2-34: Particular requirements for basic safety and essential performance of invasive blood pressure monitoring equipment
IEC 80601-2-49:2018/AMD1:2024	Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
ISO 80601-2-55:2018/AMD1:2023	Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
ISO 80601-2-56:2017/AMD1:2018	Medical Electrical Equipment - Part 2-56: Particular Requirements For Basic Safety And Essential Performance Of Clinical Thermometers For Body Temperature Measurement

ISO 80601-2-61: 2017, COR1:2018	Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
IEEE ANSI C63.27:2021	American National Standard for Evaluation of Wireless Coexistence
ANSI/AAMI EC57:2012	Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms
IEC 62304:2006+AMD1:2015 CSV	Medical device software. Software life-cycle processes
ISO 14971:2019	medical devices - application of risk management to medical devices
ISO 15223-1:2021	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements

Comparison to Predicate and Reference Devices

	Predicate device ***Patient Monitor, Model: iX10, iX12, iX15***	***Proposed device*** ***Vista 300 / Vista 300 S***	***Reference device(s)***
Manufacturer	Edan Instruments, Inc.	Shanghai Draeger Medical Instrument Co., Ltd.	N/A
510(k) number	K232962	K252250	N/A
Regulation number	21 CFR 870.1025	21 CFR 870.1025	N/A
Classification description	Arrhythmia detector and alarm (including ST-segment measurement and alarm)	Arrhythmia detector and alarm (including ST-segment measurement and alarm)	N/A
Regulatory class	Class II	Class II	N/A
Product Code	MHX, monitor, physiological, patient (with arrhythmia detection or alarms)	MHX, monitor, physiological, patient (with arrhythmia detection or alarms)	N/A
1. Intended Use/ Indications for Use			

Intended Use/ Indications for Use	The iX series Patient Monitors including iX10, iX12, iX15 are intended to be used for monitoring, storing, recording, and reviewing of, and to generate alarms for, multiple physiological parameters of adults and pediatrics (including neonates). The monitors are intended for use by trained healthcare professionals in hospital environments. The monitored physiological parameters include: ECG, respiration (RESP), temperature (TEMP), functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), carbon dioxide (CO2), cardiac output (C.O.), and Anaesthesia gas (AG). The arrhythmia detection and ST Segment analysis are intended for adult patients. The NIBP monitoring supports iCUFS algorithm and **iFAST** algorithm. The iCUFS algorithm is intended for adult, pediatric and neonatal patients. The **iFAST** algorithm is intended for adult and pediatric patients (≥3 years of age). Both measurement algorithms are also intended for use with pregnant women, including pre-eclamptic patients. NIBP MAP is not applicable to pregnant women.	Vista 300: The monitors are intended to be used for monitoring, storing, recording and reviewing of, and to generate alarms for, multiple physiological parameters of adults, pediatrics and neonates. The monitors are intended for use by trained healthcare professionals in hospital environments. The monitored physiological parameters include: ECG, respiration (RESP), temperature (TEMP), oxygen saturation of arterial blood (SpO2), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), carbon dioxide (CO2), cardiac output (C.O.), anesthetic Gas (AG), **bispectral index™ (BIS)**, **neuromuscular transmission (NMT)**. The monitors are not intended for MRI environments. Vista 300 S: The monitors are intended to be used for monitoring, storing, recording and reviewing of, and to generate alarms for, multiple physiological parameters of adults, pediatrics and neonates. The monitors are intended for use by trained healthcare professionals in hospital environments. The monitored physiological parameters include: ECG, respiration (RESP), temperature (TEMP),	ASPECT BISx (K040183) and BISx4 (K052981) The BISx / BISx4 is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use. The BISx / BISx4 is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals. The BISx / BISx4 may be used as an aid in monitoring the effects of certain anesthetic agents. Use of BIS monitoring to help

	Predicate device *Patient Monitor, Model: iX10, iX12, iX15*	*Proposed device* *Vista 300 / Vista 300 S*	*Reference device(s)*
	The Spot Temp with T2A module can only measure temperature of adult and pediatric (> 1 year of age) patients. The monitors are not intended for MRI environments. The cardiac output (C.O.) is only intended for adult patients.	oxygen saturation of arterial blood (SpO2), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), carbon dioxide (CO2), cardiac output (C.O.) (for adults only), anesthetic Gas (AG). The monitors are not intended for MRI environments. For Vista 300/Vista 300 S: The arrhythmia detection and ST Segment analysis are intended for adult patients. The NIBP monitoring supports iCUFS algorithm. The iCUFS algorithm is intended for adult, pediatric and neonatal patients. It is also intended for use with pregnant women, including pre-eclamptic patients. NIBP MAP is not applicable to pregnant women.	guide anesthetic administration may be associated with the reduction of the incidence of awareness with recall in adults during general anesthesia and sedation. IDMED ToFscan (K172690) The ToFscan is a neuromuscular transmission monitor for monitoring the neuromuscular block of a patient in the operating theatre, recovery room or intensive care unit.
2. Technological Characteristics – Monitoring Parameters			
ECG Monitoring			
Lead mode	3 Electrodes; 5 Electrodes; **6 Electrodes**; 10 Electrodes	3 Electrodes; 5 Electrodes; 10 Electrodes	N/A

		Predicate device ***Patient Monitor, Model: iX10, iX12, iX15***	***Proposed device*** ***Vista 300 / Vista 300 S***	***Reference device(s)***
Measurement range		- ADU: 15 bpm to 300 bpm - PED/NEO: 15 bpm to 350 bpm	- ADU: 15 bpm to 300 bpm - PED/NEO: 15 bpm to 350 bpm	N/A
Arrhythmia analysis		16 different arrhythmia analyses: ASYSTOLE TACHY VFIB/VTAC BRADY VT> 2 MISSED BEATS COUPLET IRR BIGEMINY PNC TRIGEMINY PNP R ONT VBRADY PVC VEN	16 different arrhythmia analyses: ASYSTOLE TACHY VFIB/VTAC BRADY VT> 2 MISSED BEATS COUPLET IRR BIGEMINY PNC TRIGEMINY PNP R ONT VBRADY PVC VEN	N/A
ST Value	Measurement range	-2.0 mV to +2.0 mV	-2.0 mV to +2.0 mV	N/A
	Accuracy	-0.8 mV to +0.8 mV: ±0.02 mV or 10%, whichever is greater. Beyond this range: not specified	-0.8 mV to +0.8 mV: ±0.02 mV or 10%, whichever is greater. Beyond this range: not specified	N/A
Pace	Pulse Indicator	- Amplitude: ±2 mV to ±700 mV - Width: 0.1 ms to 2.0 ms - Ascending time: 10 µs to 100 µs	- Amplitude: ±2 mV to ±700 mV - Width: 0.1 ms to 2.0 ms - Ascending time: 10 µs to 100 µs	N/A
	Pulse Rejection	- Amplitude: ±2 mV to ±700 mV - Width: 0.1 ms to 2.0 ms - Ascending time: 10 µs to 100 µs	- Amplitude: ±2 mV to ±700 mV - Width: 0.1 ms to 2.0 ms - Ascending time: 10 µs to 100 µs	N/A

		Predicate device *Patient Monitor, Model: iX10, iX12, iX15*	*Proposed device* *Vista 300 / Vista 300 S*	*Reference device(s)*
PVC	Range	- ADU: (0 to 300) PVCs/ min - PED/NEO: (0 to 350) PVCs/ min	- ADU: (0 to 300) PVCs/ min - PED/NEO: (0 to 350) PVCs/ min	N/A
	Resolution	1 PVCs/min	1 PVCs/min	N/A
Pause/min	Range	ADU/PED/NEO: (0 to 30) pauses/min	ADU/PED/NEO: (0 to 30) pauses/min	N/A
	Resolution	1 pause/min	1 pause/min	N/A
HR	Measurement range	- ADU: 15 bmp to 300 bmp - PED/NEO: 15 bmp to 300 bmp	- ADU: 15 bmp to 300 bmp - PED/NEO: 15 bmp to 300 bmp	N/A
	Accuracy	±1% or 1 bpm, whichever is greater	±1% or 1 bpm, whichever is greater	N/A
	Resolution	1 bpm	1 bpm	N/A
QT Analysis	QT/QTc/QTc	- QT Range: 200 ms to 800 ms - QT Resolution: 4 ms - QT Accuracy: ±30 ms - QTc Range :200ms to 800 ms - QTc Resolution:1 ms - ΔQTc Range: -600 ms to 600 ms - ΔQTc Resolution:1 ms	- QT Range: 200 ms to 800 ms - QT Resolution: 4 ms - QT Accuracy: ±30 ms - QTc Range :200ms to 800 ms - QTc Resolution:1 ms - ΔQTc Range: -600 ms to 600 ms - ΔQTc Resolution:1 ms	N/A
RESP Monitoring				
Method		Impedance between RA-LL, RA-LA	Impedance between RA-LL, RA-LA	N/A
RR Measuring Range		0 rpm to 200 rpm	0 rpm to 200 rpm	N/A
NIBP Monitoring				
Technique		Oscillometry	Oscillometry	N/A
Mode		Manual, Interval, Continuous, Sequence	Manual, Interval, Continuous, Sequence	N/A

		Predicate device ***Patient Monitor, Model: iX10, iX12, iX15***	***Proposed device*** ***Vista 300 / Vista 300 S***	***Reference device(s)***
Measurement range		<table><tr><td></td><td>Adult</td><td>Pediatric</td><td>Neonate</td></tr><tr><td>Systolic</td><td>25-290</td><td>25-240</td><td>25-140</td></tr><tr><td>Diastolic</td><td>10-250</td><td>10-200</td><td>10-115</td></tr><tr><td>Mean</td><td>15-260</td><td>15-215</td><td>15-125</td></tr></table>	<table><tr><td></td><td>Adult</td><td>Pediatric</td><td>Neonate</td></tr><tr><td>Systolic</td><td>25-290</td><td>25-240</td><td>25-140</td></tr><tr><td>Diastolic</td><td>10-250</td><td>10-200</td><td>10-115</td></tr><tr><td>Mean</td><td>15-260</td><td>15-215</td><td>15-125</td></tr></table>	N/A
Accuracy		- Maximum average error: ±5 mmHg - Maximum standard deviation: 8 mmHg	- Maximum average error: ±5 mmHg - Maximum standard deviation: 8 mmHg	N/A
Resolution		1 mmHg	1 mmHg	N/A
Maximum measuring period		- Adult/ Pediatric 120s - Neonate 90s	- Adult/ Pediatric 120s - Neonate 90s	N/A
Overpressure protection		- Adult 297 ± 3 mmHg - Pediatric 245 ± 3 mmHg - Neonate 147 ± 3 mmHg	- Adult 297 ± 3 mmHg - Pediatric 245 ± 3 mmHg - Neonate 147 ± 3 mmHg	N/A
Measuring Interval in AUTO Mode (unit: minute)		1/2/2.5/3/4/5/10/15/30/60/90/120/180/240/360/480 and **User Define**	1/2/2.5/3/4/5/10/15/30/60/90/120/180/240/360/480	N/A
Continuous		5 min, interval is 5 s	5 min, interval is 5 s	N/A
PR from NIBP	Measurement range	40 bpm to 240 bpm	40 bpm to 240 bpm	N/A
	Accuracy	±3 bpm or 3.5%, whichever is greater	±3 bpm or 3.5%, whichever is greater	N/A
	Resolution	1 bpm	1 bpm	N/A
SpO2 Monitoring [Covering the Pulse Rate (PR)]				

	Predicate device ***Patient Monitor, Model: iX10, iX12, iX15***	***Proposed device*** ***Vista 300 / Vista 300 S***	***Reference device(s)***
Information - Module **#1**	- Edan module	N/A	N/A
Information - Module **#2**	- Nellcor module	- Nellcor module	N/A
Measurement range	1% to 100%	1% to 100%	N/A
Information - Module **#3**	N/A	- **Supports Masimo module**	Draeger IACS (K203088)
TEMP Monitoring			
Number of channels	2	2	N/A
Measurement range	0 °C to 50 °C (32 °F to 122 °F)	0 °C to 50 °C (32 °F to 122 °F)	N/A
IBP Monitoring			
Measurement range	- IART, Ao, UAP, BAP, FAP, LV, P1-P4: (-50 to +400) mmHg - PA: (-6 to +120) mmHg - CVP, ICP, LAP, RAP, UVP: (-10 to +40) mmHg	**(-50 to +360)** mmHg	N/A
C.O. Monitoring			
Technique	Thermodilution Technique	Thermodilution Technique	N/A
Measurement range	- C.O.: 0.1 to 20 L/min - TB: 23°C to 43°C (73.4 °F to109.4 °F) - TI: -1 °C to 27 °C (30.2 °F to 80.6 °F)	- C.O.: 0.1 to 20 L/min - TB: 23°C to 43°C (73.4 °F to109.4 °F) - TI: -1 °C to 27 °C (30.2 °F to 80.6 °F)	N/A
CO2 Monitoring			
Information - Module **#1**	- EDAN module	- EDAN module	N/A

	Predicate device ***Patient Monitor, Model: iX10, iX12, iX15***	***Proposed device*** ***Vista 300 / Vista 300 S***	***Reference device(s)***
Intended Patient	Adult, pediatric, neonatal	Adult, pediatric, neonatal	N/A
Measure Parameters	etCO2, FiCO2, AwRR	etCO2, FiCO2, AwRR	N/A
Measuring Range	- etCO2:0 mmHg to **150** mmHg (0%to 20%) - FiCO2:0 mmHg to 50 mmHg - AwRR:0 rpm to 150 rpm	- etCO2:0 mmHg to **152** mmHg (0%to 20%) - FiCO2:0 mmHg to 50 mmHg - AwRR:0 rpm to 150 rpm	N/A
Information - Module **#2**	- Respironics module	- Supports Dräger module	Draeger CO_2 Mainstream Sensor (K221118) - Mainstream CO_2 Oridion Medical 1987 Capnostream™ 35 Portable Respiratory Monitor (K150272) - Microstream CO2 - MicroPod Covidien Microstream CO2 NanoPod (K213911) - Microstream CO2 - NanoPod
AG Monitoring			
Information - Module **#1**	- EDAN G7 Module	N/A	N/A

	Predicate device *Patient Monitor, Model: iX10, iX12, iX15*	*Proposed device* *Vista 300 / Vista 300 S*	*Reference device(s)*
Information - Module **#2**	- Masimo Module	N/A	N/A
BIS Monitoring			
Module information	N/A	- **Supports Covidien module**	ASPECT BISx (K040183) and BISx4 (K052981)
NMT Monitoring			
Module information	N/A	- **Supports IDMED module**	IDMED ToFscan (K172690)
Clinical Assistive Applications			
Score System	MEWS, **NEWSM** NEWS2, **PEWS**	MEWS, NEWS2	N/A
3. Technological Characteristics – Hardware			

<table>
<tr><th></th><th>Predicate device
Patient Monitor, Model: iX10, iX12, iX15</th><th>Proposed device
Vista 300 / Vista 300 S</th><th>Reference device(s)</th></tr>
<tr><td>Interfaces</td><td>
<table>
<tr><td>Interface Name</td><td>Interface Type</td><td>Interface Quantity</td></tr>
<tr><td>Analog Output</td><td>Output</td><td>1</td></tr>
<tr><td>Defibrillator Synchronization</td><td>Output</td><td>1</td></tr>
<tr><td>Nurse Call</td><td>Output</td><td>1</td></tr>
<tr><td>USB Interfaces</td><td>Input, Output</td><td>4</td></tr>
<tr><td>Video Output Interface</td><td>Output</td><td>1</td></tr>
<tr><td>RS232 Interface</td><td>Input, Output</td><td>1</td></tr>
<tr><td>Network interface</td><td>Input, Output</td><td>1</td></tr>
<tr><td>AC power interface</td><td>Input</td><td>iX10: 1
iX12/iX15: 0</td></tr>
<tr><td>Wi-Fi</td><td>Input, Output</td><td>1</td></tr>
<tr><td>E-Link</td><td>Input, Output</td><td>1</td></tr>
</table>
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<tr><td>Video Output Interface</td><td>Output</td><td>1</td></tr>
<tr><td>RS232 Interface</td><td>Input, Output</td><td>2</td></tr>
<tr><td>Network interface</td><td>Input, Output</td><td>1</td></tr>
<tr><td>AC power interface</td><td>Input</td><td>1</td></tr>
<tr><td>Wi-Fi</td><td>Input, Output</td><td>1</td></tr>
</table>
</td><td>N/A</td></tr>
</table>

		Predicate device *Patient Monitor, Model: iX10, iX12, iX15*	*Proposed device* *Vista 300 / Vista 300 S*	*Reference device(s)*
Power supply		- AC Voltage 100 V to 240 V~ - Input Current **1.6 A to 0.8 A** - Frequency 50 Hz/60 Hz	- AC Voltage 100 V to 240 V~ - Input Current ⩽ **2.0 A** - Frequency 50 Hz/60 Hz	N/A
Rechargeable Battery		Yes	Yes	N/A
4. Technological Characteristics – Network/ Communications				
WI-FI	IEEE	802.1la/b/g/n	802.11a/b/g/n	N/A
	Frequency Band	2.4 GHz ISM band 5 G ISM band	2.4 GHz ISM band & 5 GHz ISM band	N/A

NOTE: Differences between the predicate and proposed device are explicitly highlighted in the comparison table by light blue cell shading and by rendering the relevant items in **bold** text.

The differences between the Vista 300/Vista 300 S and the predicate device, as detailed in the comparison table above, do **not impact device output, performance, or safety**. For all alternative modules (such as Masimo SpO_2, BIS, NMT, and CO_2), the Vista 300/Vista 300 S only receives and displays values that have already been processed by FDA-cleared and individually marketed modules. The proposed device does not modify hardware, signal acquisition/processing or algorithm logic that could affect the reported physiological parameters.

All differences have been assessed through comprehensive verification and validation testing, as described in the Non-clinical Testing section. These tests were conducted according to recognized consensus standards and included system integration evaluations. The results confirm that the outlined differences do not affect the device's accuracy, reliability, or safety.

Therefore, the non-clinical testing provided and/or referenced in this submission remains fully applicable and supports the substantial equivalence of the Vista 300/Vista 300 S to the predicate device, despite the enumerated differences.

Discussion of Non-clinical Testing

The Vista 300/Vista 300 S is a new Dräger device to be cleared in the USA that has undergone extensive verification and validation to demonstrate conformity with applicable national and international consensus standards, and other regulatory expectations. These nonclinical tests were conducted using well-established methods and are included in this submission to establish substantial equivalence to the predicate device.

- Electrical safety
- Electromagnetic compatibility (EMC)
- Software, including cybersecurity
- IEC 60601-1-8:2006+AMD2:2020 for alarm systems
- IEC 60601-2-10: 2012+AMD1:2016 for Nerve and Muscle Stimulators
- IEC 60601-2-25:2011 for electrocardiographs
- IEC 80601-2-26:2019/AMD1:2024 for Electroencephalographs
- IEC 60601-2-27:2011 for electrocardiographic monitoring equipment
- IEC 80601-2-30:2018 for automated non-invasive sphygmomanometers
- IEC 60601-2-34:2024 for invasive blood pressure monitoring equipment
- IEC 60601-2-49:2018/AMD1:2024 for multifunction patient monitoring equipment
- ISO 80601-2-55:2018/AMD1:2023 for respiratory gas monitors
- ISO 80601-2-56:2017/AMD1:2018 for body temperature measurement
- ISO 80601-2-61:2017, COR1:2018 for pulse oximeter equipment
- IEEE ANSI C63.27:2021 for Wireless Coexistence
- ANSI AAMI EC57:2012 for cardiac rhythm and ST segment measurement algorithms

Conclusion

The conclusions drawn from non-clinical tests and the comparison of intended use and technological characteristics with its predicate and reference devices demonstrate that the new product Vista 300/Vista 300 S is as safe, as effective and performs as well as the legally marketed predicate device K232962.

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