



April 24, 2026

Shanghai Draeger Medical Instrument Co., Ltd.
Xuguang Miao
Senior Regulatory Affairs Specialist
No.229 HuPo Road, Shanghai International Medical Zone
Pudong New Area
Shanghai, 201321
China

Re: K250349

Trade/Device Name: Vista CMS

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

Dated: March 25, 2026

Received: March 25, 2026

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the Quality 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,

KIMBERLY N. CROWLEY
-S

For: 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

510(k) Number (if known)
K250349

Device Name
Vista CMS

Indications for Use (Describe)

Vista central monitoring software (hereinafter referred to as Vista CMS) supports centralized management of patients' clinical data provided by Vista Series patient monitors. Clinicians can obtain patient clinical data from networked devices via Vista CMS. The functionalities of Vista CMS include:

- Viewing patient real-time clinical data and alarms.
- Storing and reviewing patient clinical data and alarms.
- Printing real-time and history patient data.
- Configuring local settings as well as synchronizing settings to a remote device through network.
- Accessing patient clinical data between several departments.

Vista CMS is intended to be used only in clinical or hospital environment by well-trained healthcare professionals.

Vista CMS is indicated for use when monitoring adult and/or pediatric and/or neonate patients as indicated by labeling of the medical device providing the data.

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

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Premarket Notification Summary

Submitter: Shanghai Draeger Medical Instrument Co., Ltd.
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Establishment's registration number: 3019545235

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Date prepared: April 23, 2026

Device Name: Trade name: Vista CMS
Common name: Vista CMS
Classification name: Monitor, Physiological, Patient
(With Arrhythmia Detection Or Alarms)
Regulation number: 21 CFR § 870.1025
Product code: MHX
Class: II

Predicate device: Central Monitoring System (MFM-CMS), K232694

Device Description

Vista CMS is a software-only networked patient monitoring system intended to provide clinicians central monitoring in professional healthcare facilities. The system that integrates and displays patient information from networked monitoring devices can be configured to restrict controls and access based on user role, supporting the user in securely delivering quality patient care.

Vista CMS Central Monitoring System supports to display, store, print, and transfer information received from the compatible monitoring devices as well as bi-directional configuration of the compatible monitors.

Intended Use/Indications for Use

Vista central monitoring software (hereinafter referred to as Vista CMS) supports centralized management of patients' clinical data provided by Vista Series patient monitors. Clinicians can obtain patient clinical data from networked devices via Vista CMS. The functionalities of Vista CMS include:

- Viewing patient real-time clinical data and alarms.
- Storing and reviewing patient clinical data and alarms.
- Printing real-time and history patient data.
- Configuring local settings as well as synchronizing settings to a remote device through network.
- Accessing patient clinical data between several departments.

Vista CMS is intended to be used only in clinical or hospital environment by well-trained healthcare professionals.

Vista CMS is indicated for use when monitoring adult and/or pediatric and/or neonate patients as indicated by labeling of the medical device providing the data.

Comparison to Predicate

-	<i>Proposed device Vista CMS</i>	<i>Predicate device Central Monitoring System (MFM-CMS)</i>	<i>Comments</i>
Manufacturer	Shanghai Draeger Medical Instrument Co., Ltd.	Edan Instruments, Inc.	-
510(k) number	K250349	K232694	-
Regulation number	21 CFR 870.1025	21 CFR 870.1025	Same
Classification description	Arrhythmia detector and alarm (including ST-segment measurement and alarm)	Arrhythmia detector and alarm (including ST-segment measurement and alarm)	Same
Regulatory class	Class II	Class II	Same
Product code	MHX	MHX	Same
1. Intended Use			

-	<i>Proposed device</i> <i>Vista CMS</i>	<i>Predicate device</i> <i>Central Monitoring System (MFM-CMS)</i>	<i>Comments</i>
Intended Use/ Indications for Use	<p>Vista central monitoring software (hereinafter referred to as Vista CMS) supports centralized management of patients' clinical data provided by Vista Series patient monitors. Clinicians can obtain patient clinical data from networked devices via Vista CMS. The functionalities of Vista CMS include:</p> <ul style="list-style-type: none"> - Viewing patient real-time clinical data and alarms. - Storing and reviewing patient clinical data and alarms. - Printing real-time and history patient data. - Configuring local settings as well as synchronizing settings to a remote device through network. - Accessing patient clinical data between several departments. <p>Vista CMS is intended to be used only in clinical or hospital environment by well-trained healthcare professionals.</p> <p>Vista CMS is indicated for use when monitoring adult and/or pediatric and/or neonate patients as indicated by labeling of the medical device providing the data.</p>	<p>MFM-CMS Central Monitoring System (hereinafter referred to as MFM-CMS) supports centralized management of patients' clinical data provided by EDAN medical devices. Clinicians can obtain patient clinical data via MFM-CMS. The indications for use of the MFM-CMS central monitoring system include:</p> <ul style="list-style-type: none"> - Viewing patient real-time clinical data and alarms. - Storing and reviewing patient clinical data and alarms. - Printing real-time and history patient data. - Configuring local settings as well as synchronizing settings to a remote device through network. - Accessing patient clinical data between several departments. <p>MFM-CMS is intended to be used only in clinical or hospital environment by well-trained healthcare professionals.</p> <p>MFM-CMS is indicated for use when monitoring adult and/or pediatric and/or neonate patients as indicated by labeling of the medical device providing the data.</p>	Same
Contraindications	None	None	Same

		<i>Proposed device Vista CMS</i>		<i>Predicate device Central Monitoring System (MFM-CMS)</i>		<i>Comments</i>
-						
Patient population		<ul style="list-style-type: none"> • Adult • Pediatric • Neonate 		<ul style="list-style-type: none"> • Adult • Pediatric • Neonate 		Same
Intended user		Well-trained healthcare professionals		Well-trained healthcare professionals.		Same
Environments of use		Hospital or clinical environment		Hospital or clinical environment.		Same
Conclusion		As determined in the above, the proposed device’s Intended Use is substantially equivalent to the predicate device.				
2. Technological Characteristics – Hardware as recommended [not part of the medical device to be cleared]						
System Components		Vista CMS requires the following hardware to run and function optimally: <ul style="list-style-type: none"> - Clients (Monitoring Station, Viewer Station) - Computer platform (to be provided by user) - Network devices (to be provided by user) - Printer (to be provided by user) - UPS (to be provided by user) 		MFM-CMS Central Monitoring System consists of the following components: <ul style="list-style-type: none"> - Central Station - Viewer Station (optional) - Computer platform (to be provided by user) - Network devices (to be provided by user) - Printer (to be provided by user) - UPS (to be provided by user) 		Same
PC workstation (Recommended configuration)	Monitoring Station Server Terminal	CPU	Intel Core i5, 3rd generation, Quad 3.1 GHz or above	CPU	Intel Core i5, 3rd generation, Quad 3.1 GHz or above	Different
		Memory	At least 8 G	Memory	At least 8 G	
		Hard disk	At least 1 T	Hard disk	At least 1 T	
		Display interface	2 or above (at least one VGA interface and one HDMI interface)	Display interface	2 or above (at least one VGA interface and one HDMI interface)	
		LAN port	2 or above	LAN port	2 or above	

-		<i>Proposed device Vista CMS</i>		<i>Predicate device Central Monitoring System (MFM-CMS)</i>		<i>Comments</i>
		USB port	2 or above	USB port	2 or above	
		Operating system	Windows 11 Pro 64-bit, Server 2016 OS, Server 2019, Server 2022, virtual machine	Operating system	Windows 10 Pro 32/64 bit, Windows 11 Pro 64-bit, Server 2012, Server 2016 OS, virtual machine	
	Viewer Station	CPU	Intel Core i5, Duo 3.1 GHz or above	CPU	Intel Core i5, 3rd generation, Quad 3.1 GHz or above	Same
		Memory	At least 4 G	Memory	At least 4 G	
		Hard disk	At least 120 GB	Hard disk	At least 120 GB	
		Display interface	2 or above (at least one VGA interface and one HDMI interface)	Display interface	2 or above (at least one VGA interface and one HDMI interface)	
		LAN port	2 or above	LAN port	2 or above	
		USB port	4 or above	USB port	4 or above	
Operating system	Windows 11 Pro 64-bit	Operating system	Windows 10 Pro 32/64 bit, Windows 11 Pro 64-bit			
Display	Dimensions (inch)	Dimensions (inch)	Dimensions (inch)	Dimensions (inch)	Same	
	19 (widescreen)	1440X900	19 (widescreen)	1440X900		
	19 (regular-screen)	1280X1024	*19 (regular-screen)	1280X1024		
	22 (widescreen)	1920X1080	22 (widescreen)	1920X1080		
	24 (widescreen)	1920X1080	*Recommended			

-	<i>Proposed device Vista CMS</i>		<i>Predicate device Central Monitoring System (MFM-CMS)</i>		<i>Comments</i>
User interface / Input controls	PS/2 or USB keyboard, PS/2 or USB mouse		PS/2 or USB keyboard, PS/2 or USB mouse		Same
Printer	HP LaserJet series		HP LaserJet series		Same
Audio outputs	Built-in speaker is recommended		Built-in speaker is recommended		Same
Uninterruptible Power Supply (UPS)	1000 W		1000 W		Same
3. Technological Characteristics – Network/ Communication					
Network connect	Support wired and wireless network		Support wired and wireless network		Same
Network device	Structure	Ethernet 802.3	Structure	Ethernet 802.3	Same
	Device	Network switch	Device	Network switch	
	Band Width	100 Mbps (802.3u), 1000 Mbps (802.3ab/802.3z)	Band Width	100 Mbps (802.3u), 1000 Mbps (802.3ab/802.3z)	
	Transmitted information	Waveforms, parameters, and alarms of all networked bedside monitors	Transmitted information	Waveforms, parameters, and alarms of all networked bedside monitors	
	Compatible monitors	Patient monitors complying with Dräger network protocol	Compatible monitors	Patient monitors complying with EDAN network protocol	
WIFI protocol	IEEE: 802.11a/b/g/n		IEEE: 802.11a/b/g/n		Same
Bi-directional configuration	Support		Support		Same
Wired data security	TLS (Transport Layer Security)		TLS (Transport Layer Security)		Same

-	<i>Proposed device Vista CMS</i>	<i>Predicate device Central Monitoring System (MFM-CMS)</i>	<i>Comments</i>
Wireless data security	TLS (Transport Layer Security)	TLS (Transport Layer Security)	Same
4. Technological Characteristics – Software (physiological parameter)			
Parameters supported	Support the monitoring of the parameters of ECG, RESP, NIBP, SpO2, PR, TEMP, IBP, CO2, C.O., AG, and BIS parameters derived from the monitoring equipmen.	Support the monitoring of the parameters of ECG, RESP, NIBP, SpO2, PR, TEMP, IBP, CO2, C.O., AG, RM, ICG , and BIS parameters derived from the monitoring equipment.	Different
5. Technological Characteristics – Software (function)			
Alarm system function	<ul style="list-style-type: none"> - Alarm Indicators: audible and visual alarms. - Alarm Categories: Physiological Alarm, Technical Alarm, Prompts. - Alarm Priorities: High, Medium, Low. - Alarm Source and Alarm Communication Methods: Alarms, triggered by a physiological sign that appears abnormal or by technical problems of the monitoring devices, are sent to the Vista CMS by the monitoring devices and then indicated to the users by the Vista CMS. Alarms on the monitoring devices are displayed in the patient sectors and in the single bed view window. The alarm and prompts triggered by the Vista CMS are displayed in the system information area on the upper screen. 	<ul style="list-style-type: none"> - Alarm Indicators: Audible and visual alarms. - Alarm Categories: Physiological Alarm, Technical Alarm. - Alarm Priorities: High, Medium, Low, Prompts. - Alarm Source and Alarm Communication Methods: Alarms, triggered by a physiological sign that appears abnormal or by technical problems of the monitoring devices, are sent to the MFM-CMS. MFM-CMS provides visual and audible alarm indications. Most of the alarms come from bedside devices. Alarms detected by the MFM-CMS are displayed in the system information area at the top of the screen. 	Same

-	<i>Proposed device</i> <i>Vista CMS</i>	<i>Predicate device</i> <i>Central Monitoring System (MFM-CMS)</i>	<i>Comments</i>
Data Review	<ul style="list-style-type: none"> - Short trend: Latest 12 hours of short trends for all parameters. - Trend graph and trend table: Latest 720 hours of trend graph and trend table for all parameters. - Full disclosure waveforms: Latest 720 hours of ECG full size waveforms and ECG compressed waveforms. - Physiological alarm events: Latest 720 hours of the events. - NIBP review: Latest 720 hours of NIBP measurement data. - C.O. review: Latest 720 hours of C.O. measurement results. - Score trend review: Latest 720 hours of score trend results. 	<ul style="list-style-type: none"> - Most recent 12 hours of short trends for all parameters; - Most recent 720 hours of trend graph and trend table for all parameters; - Most recent 720 hours of full disclosure waveforms and ECG compressed waveforms; - Most recent 720 hours of the physiological alarm events, nurse call events, and patient call events; - Most recent 720 hours of 12-lead analysis results; - Most recent 720 hours of NIBP measurement data; - Most recent 720 hours of C.O. measurement results. - Most recent 720 hours of score trend review. 	Different
Calculations	Vista CMS provides functions including drug calculation and titration table, hemodynamic calculation, oxygenation calculation, renal function calculation and ventilation calculation.	MFM-CMS provides functions including drug calculation and titration table, hemodynamic calculation, oxygenation calculation, renal function calculation and ventilation calculation.	Same

		<i>Proposed device Vista CMS</i>	<i>Predicate device Central Monitoring System (MFM-CMS)</i>	<i>Comments</i>
Print	-	<ul style="list-style-type: none"> - Patient information - Real-time monitoring data - Alarm list or waveform - Waveform review - Trend table/graph - NIBP review - C.O. review - Score trend - Calculation result 	<ul style="list-style-type: none"> - Patient information - Real-time monitoring data - Alarm list or waveform - Waveform review - Trend table-graph - NIBP review - 12-lead analysis result - C.O. review - Score trend - ECG, NIBP - Nursing report - Calculation result 	Different
License Authorization		Support	Support	Same
Distributed function		<ul style="list-style-type: none"> - Support several CMS network. - Up to 10 Monitoring Station or 10 Viewer Station connections are supported for one Central Station. 	<ul style="list-style-type: none"> - Support several CMS network. - Up to 10 Monitoring Station or 10 Viewer Station connections are supported for one Central Station. 	Same
Maximum number of patient monitor supported		<ul style="list-style-type: none"> - The Monitoring Station can admit up to 128 Dräger physiological monitoring devices via wired or wireless connection. 	<ul style="list-style-type: none"> - The Monitoring Station can admit up to 128 EDAN physiological monitoring devices via wired or wireless connection. 	Different
6. Technological Characteristics – Environmental				
Temperature	Working	+5 °C to +40 °C(+41 °F ~+104 °F)	+5 °C to +40 °C(+41 °F ~+104 °F)	Same
	Transport and Storage	-20 °C to +55 °C(-4 °F ~+131 °F)	-20 °C to +55 °C(-4 °F ~+131 °F)	Same
Humidity	Working	15%RH ~ 95%RH (non-condensing)	15%RH ~ 95%RH (non-condensing)	Same

-		<i>Proposed device Vista CMS</i>	<i>Predicate device Central Monitoring System (MFM-CMS)</i>	<i>Comments</i>
	Transport and Storage	15%RH ~ 95%RH (non-condensing)	15%RH ~ 95%RH (non-condensing)	Same
Altitude	Working	70 kPa ~ 106 kPa	70 kPa ~ 106 kPa	Same
	Transport and Storage	70 kPa ~ 106 kPa	70 kPa ~ 106 kPa	Same
Conclusion		Based on the above, the product's technical data have been determined to be substantially equivalent to the predicate device.		

Discussion of Non-clinical Testing

- **Biocompatibility Testing:**

Not applicable.

- **Electrical safety and electromagnetic compatibility (EMC):**

Not applicable.

- **Software Verification and Validation Testing:**

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

- **Bench Testing:**

Draeger has conducted functional and system level testing to validate the performance of the devices. The results of the bench testing show that the subject device meets relevant consensus standards.

- IEC 60601-1-8:2006 + Am1:2012 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.

- **Clinical testing:**

Not applicable.

Conclusion

Based on the indications for use/intended use, technological characteristics, performance/non-clinical testing, and comparison to the predicate device, the new device is substantially equivalent to the predicate device K232694.

- END -