August 28, 2020

Draeger Medical Systems, Inc.
Thomas Ostrowski
RA Project Manager
6 Tech Dr.
Andover, Massachusetts 01810

Re: K200859
Trade/Device Name: Infinity M300
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: July 24, 2020
Received: July 27, 2020

Dear Thomas Ostrowski:

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

Jennifer Shih
Assistant Director
Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K200859

Device Name
Infinity M300

Indications for Use *(Describe)*
The Infinity M300 is intended for use with the ICS to monitor ECG and pulse oximetry on ambulatory and non-ambulatory adult and pediatric patients using wireless communication over the Infinity patient monitoring network.

The Infinity M300 with TruST is intended for 12-Lead ECG monitoring with a reduced set of electrodes. Reconstructed leads are intended for real-time assessment of ST segment changes.

Contraindications:
The Infinity M300 is not compatible for use in an MRI magnetic field.

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) SUMMARY

I. Submitter:

Draeger Medical Systems, Inc.
6 Tech Drive
Andover, MA 01810-2434

Tel: (978) 379-8002

Contact Person: Thomas Ostrowski
RA Project Manager
E-mail: tom.ostrowski@draeger.com
Date Prepared: March 30, 2020

II. Device

Names / Common Names / Classification Names:

Common Name:	Multi-parameter patient monitor
Trade Name:	Infinity M300
Classification Name:	Monitor, Physiological, Patient (with Arrhythmia detection or alarms)
Product Code:	MHX
Regulatory Class:	II
Regulation Number:	21 CFR §870.1025

III. Predicate Device:

Infinity CentralStation (VG1 MS26800) with Infinity M300 was cleared under K130711 on April 11, 2013.

IV. Device Description:

Infinity M300 device description

The Infinity M300 is a wireless telemetry, patient-worn device with rechargeable lithium-ion battery which monitors ECG and SpO2 physiological data and features a color display, local alarm alerts and keypad interface. ECG functions include heart rate, arrhythmia detection and ST segment analysis and SpO2 functions include pulse plethysmogram and pulse rate. Infinity M300 with TruST allows for 12-lead ECG monitoring with a reduced set of electrodes by deriving values for missing leads.

Infinity M300 components

The standard Infinity M300 includes the following:

– Infinity M300 patient-worn device
– Infinity M300 Bedside Charger
– Infinity M300 CentralCharger
– Infinity M300 programming kit

Infinity M300 environment of use
The Infinity M300 is intended to be used in an environment where patient care is provided by Healthcare Professionals, i.e. physicians, nurses, and technicians, trained on the use of the device, who will determine when use of the device is indicated, based upon their professional assessment of the patient's medical condition.

Infinity M300 communications
Infinity M300 connects to the Infinity network via 802.11 wireless communication with hospital access points (AP). From the AP, data is routed over the Infinity network via wired Ethernet for real-time display and annunciation at the Infinity CentralStation Wide (Widescreen), the Dräger central monitoring workstation. The Infinity CentralStation (ICS) Wide allows for simultaneous central monitoring of up to thirty-two (32) Infinity M300 devices to support wireless telemetry monitoring.

Infinity M300 user interfaces and functions
The Infinity M300 communicates bilaterally with the Infinity CentralStation (ICS) central nursing workstation which serves as the primary display, user interface and alarm annunciator for acquired M300 physiological patient data. The Infinity M300 local keypad and display serves as a secondary user interface for clinicians to access local features and functions.

To facilitate patient mobility clinicians can place the Infinity M300 in a disposable or re-usable shower pouch to be worn by the patient. When a patient is sedentary (in bed or sitting) the clinician can place the Infinity M300 in the Bedside Charger to provide a slow charge for the device. When the Infinity M300 is not in clinical use, it may be stored and recharged at an accelerated rate in the CentralCharger.

V. Indications for Use / Intended Use:

The Infinity M300 is intended for use with the ICS to monitor ECG and pulse oximetry on ambulatory and non-ambulatory adult and pediatric patients using wireless communication over the Infinity patient monitoring network.

The Infinity M300 with TruST is intended for 12-Lead ECG monitoring with a reduced set of electrodes. Reconstructed leads are intended for real-time assessment of ST segment changes.

Contraindications:

The Infinity M300 is not compatible for use in an MRI magnetic field.

VI. Comparison of Technological Characteristics with the Predicate Device:

The intended use, performance and technological characteristics are substantially equivalent to the referenced predicate device. In comparison to the predicate device, the modified Infinity M300 VG2.4 has the same intended use, indications for use, packaging materials and shelf life. Proposed modifications do not change the fundamental scientific technology of the cleared device. The Infinity M300 VG2.4 differs from the predicate device in regards to the significant change modifications below:

Significant Change Modifications introduced in this submission:

- ST Algorithm modifications
- ECG/Arrhythmia Algorithm modifications
  - QRS Detection enhancements
  - Arrhythmia enhancements

VII. Performance Data

Verification Testing:

Dräger evaluated the device with proposed modifications through verification testing and risk assessment of the device with proposed modifications and identified the need for software design mitigations to support the ECG/Arrhythmia algorithm and QRS Threshold modifications. The risk control measure was designed, developed and tested in accordance with 21 CFR 820.30 design controls. The results of Verification testing confirm the modified device continues to meet the criteria for substantial equivalence to the predicate device.

Validation Testing:

Dräger design controls in compliance with 21 CFR 820.30 (g) govern validation and risk analysis of device modifications. Dräger 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 effective implementation of software design input requirements, established risk mitigations and effective user adoption of the proposed modifications. Validation test results support substantial equivalence to the predicate device.

Biocompatibility:

Dräger design controls in compliance with 21 CFR 820.30 govern the assessment of materials used in the Infinity M300. Dräger selected materials appropriate for the use-case of the device per FDA's guidance document "*Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*.'" Considering the intended use of the device and the

transient nature of skin contact, an assessment was made for compliance to ISO 10993-1 and appropriate methods of testing were conducted on the materials. The results of testing and assessment demonstrate materials are biocompatible for their intended use and support substantial equivalence with the predicate device.

Sterilization:

Infinity M300 does not require sterilization to accomplish its intended use. Reprocessing of the Infinity M300 follows the criteria for low level cleaning and disinfecting.

Standards / Compliance testing:

Infinity M300 with proposed modifications has been tested for compliance with the following standards in support of Electrical Safety, EMC and particular standards requirements:

AAMI/ANSI ES60601-1	2005/(R)2012 and A1:2012	Medical electrical equipment – Part 1: General Requirements for Basic Safety and Essential Performance
IEC60601-1-2	Edition 4.0 2014-02	Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
IEC60601-2-27	Edition 3.0 2011-03	Medical electrical equipment – Part 2-27: Particular requirements for the safety of electrocardiographic monitoring equipment
ANSI/AAMI EC57	2012	Testing And Reporting Performance Results Of Cardiac Rhythm And ST-Segment Measurement Algorithms

VIII. Conclusion

Substantial Equivalence:

Infinity M300 with VG2.4 significant change modifications is substantially equivalent to the predicate device as cleared under K130711 on April 11, 2013. The intended use of the Infinity M300 VG2.4 as described in the product labeling has not changed as a result of the proposed modifications. The results of verification and validation for the proposed modifications support substantial equivalence to the predicate device.