June 21, 2024

Merge Healthcare Incorporated
Carol Nakagawa
Senior Regulatory Affairs Manager
900 Walnut Ridge Drive
Hartland, Wisconsin 53029

Re: K233326
Trade/Device Name: Merge Hemo, Model RCSV2
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: September 29, 2023
Received: September 29, 2023

Dear Carol Nakagawa:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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.

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,

Robert T. Kazmierski -S

for

LCDR Stephen Browning
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.

Submission Number *(if known)*

K233326

Device Name

Merge Hemo, Model RCSV2

Indications for Use *(Describe)*

Merge Hemo displays, measures, and records physiological data from patients undergoing invasive catheter-based diagnostic and interventional procedures.

The Hemo System can visualize and capture vital sign values including ECG, impedance respiration, SpO_2 and Pleth waveforms, invasive blood pressure, temperature, non-invasive blood pressure (NIBP), Thermodilution cardiac output and Fractional Flow Reserve (FFR). The system can display and capture 12 Lead resting ECG to visualize arrhythmias, and ST-segment changes. Some Hemo systems have an option to measure and display Side-stream End Tidal Carbon Dioxide ($EtCO_2$) along with apnea and respiration rates calculated from the $EtCO_2$ waveforms. The system can also perform specified calculations from captured or manually entered values.

The hemodynamic portion of the system is comprised of the Patient Data Module (PDM) and the Merge Hemo Monitor PC.

All vital parameters are acquired in the PDM. This data is then transmitted to the Merge Hemo Monitor PC. All data can then be displayed on the Merge Hemo Monitor PC. User-adjustable visual alarms available in the system alert the operator to anomalous occurrences and facilitate timely responses.

Patient allergies and current medication information can be entered by the user and displayed by the system. If desired and using a third-party database, the Hemo system can display drug to drug or drug-to-allergy interaction information.

The Merge Hemodynamic system is intended for use in invasive catheter-based diagnostic and interventional procedure laboratories and in pre- and post-procedure care areas in professional health care facilities. The Merge Hemo system is intended for use under the close supervision of qualified medical personnel. The system is not intended for unattended patient monitoring or in situations where arrhythmia detection is required. This system is used in the diagnosis and treatment of cardiovascular, peripheral vascular, and cardiac diseases. The system is designed for patients of Infant to Adult ages. The system is to be used in invasive procedural laboratories under the direct supervision of physicians, nurses, and technicians.

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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Merge
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510(k) Summary

I. Submitter Information

Submitter:	Merge Healthcare Incorporated 900 Walnut Ridge Drive Hartland, Wisconsin 53209 USA Phone: 262-367-0700
Contact Person:	Carol Nakagawa Principal, Regulatory Affairs Phone: 289-902-0129 Email: carol.nakagawa@merative.com Email: med.reg.contact@merative.com
Secondary Contact Person:	Nadia Marchant VP, Regulatory Affairs and Quality Assurance Phone: 262-367-0700 Email: nadia.marchant@merative.com

Date Prepared: May 24, 2024

II. Device

Device Trade Name:	Merge Hemo™, Model RCSV2
Common Name:	Hemodynamic monitoring system
Classification Name:	Programmable diagnostic computer
Regulation Number:	21 CFR 870.1425
Device Class:	Class II
Product Code:	DQK

III. Predicate Device

Device Trade Name:	Merge Hemo
510(k) Number:	K152864
Regulation Number:	21 CFR 870.1425
Device Class:	Class II
Product Code:	DQK

IV. Device Description

The Merge Hemo, Model RCSV2 device is a hemodynamics recording computer system that monitors, measures, displays, records and stores various physiologic and blood flow parameters based on the output from one or more electrodes, transducers, or measuring devices. The system is used for documenting and monitoring patients undergoing diagnostic and interventional catheter-based procedures. The procedures can be performed in the clinical areas of invasive cardiology, interventional radiology, and cardiac electrophysiology.

The device consists of off-the-shelf computer hardware such as personal computers and servers, a Patient Data Module (PDM) that acquires patient vitals received from accessories such as ECG electrodes, invasive catheters/pressure transducers, and temperature probes, and transmits them to the Merge Hemo Monitor.

The Merge Hemo system includes a Record Station Workstation with options to add a Procedure Room Hemo Monitor or a Remote Operators Terminal (ROT). The Record Station Workstation for Merge Hemo, Model RCSV2 is made up of medical grade Hemo Client and Hemo Monitor All-in-One computers with built-in display monitors.

The new PDM component, the ARGUS PB-3000 manufactured by Schiller AG, acquires the following patient vitals: ECG, Invasive Blood Pressure, SpO_2, Non-Invasive Blood Pressure, Temperature, Cardiac Output, and CO_2, digitizes the signals, and transmits them to the Hemo Monitor in the Record Station. The Client side of the Record Station is responsible for the documentation, display, storage, and distribution of the data acquired during the procedure.

V. Indications for Use / Intended Use

Indications for Use / Intended Use Statement

The Merge Hemo System displays, measures, and records physiological data from patients undergoing invasive catheter-based diagnostic and interventional procedures.

The Merge Hemo System can visualize and capture vital sign values including ECG, impedance respiration, SpO_2 and Pleth waveforms, invasive blood pressure, temperature, non-invasive blood pressure (NIBP), Thermodilution cardiac output and Fractional Flow Reserve (FFR). The system can display and capture 12 Lead resting ECG to visualize arrhythmias, and ST-segment changes. Some Hemo systems have an option to measure and display Side-stream End Tidal Carbon Dioxide ($EtCO_2$) along with apnea and respiration rates calculated from the $EtCO_2$ waveforms. The system can also perform specified calculations from captured or manually entered values.

The hemodynamic portion of the system is comprised of the Patient Data Module (PDM) and the Merge Hemo Monitor PC.

All vital parameters are acquired in the PDM. This data is then transmitted to the Merge Hemo Monitor PC. All data can then be displayed on the Merge Hemo Monitor PC. User-adjustable visual alarms available in the system alert the operator to anomalous occurrences and facilitate timely responses.

Patient allergies and current medication information can be entered by the user and displayed by the system. If desired and using a third-party database, the Hemo system can display drug to drug or drug-to-allergy interaction information.

The Merge Hemo system is intended for use in invasive catheter-based diagnostic and interventional procedure laboratories and in pre-and post-procedure care areas in professional health care facilities. The Merge Hemo system is intended for use under the close supervision of qualified medical personnel. The system is not intended for unattended patient monitoring or in situations where arrhythmia detection is required. This system is used in the diagnosis and treatment of cardiovascular, peripheral vascular, and cardiac diseases. The system is designed for patients of Infant to Adult ages. The system is to be used in invasive procedural laboratories under the direct supervision of physicians, nurses, and technicians.

Comparison

The Indications for Use statement for Merge Hemo Model RCSV2 is not identical to the predicate device. The Indications for Use statement for the subject device was revised to reflect technological changes made to the subject device, to add the circumstances when hemodynamic monitoring is performed, to modernize references to reflect how invasive catheterization procedures and procedure room (cath lab) environments are described, and to remove unnecessary information. The differences do not change the intended use of the device and do not affect the safety and effectiveness of the device compared to the predicate. The subject and predicate devices are both intended to perform hemodynamic recording and display for patients undergoing invasive catheterization procedures in the cath lab.

VI. Comparison of Technological Characteristics with the Predicate Device

The subject device Merge Hemo, Model RCSV2, is a line extension of the predicate device, which is Merge Healthcare's 510(k) cleared Merge Hemo (K152864).

The subject and predicate devices share the same technological principles used to perform hemodynamic monitoring and recording with Merge Hemo software running on personal computer hardware and on a computer server, as well as for receiving digitized patient vitals signals from a Patient Data Module manufactured by Schiller AG.

- The same patient vital parameters are monitored
- Full Disclosure recordings are captured by the Hemo Monitor computer
- Calculations of the same physiological parameters are performed using the same software algorithms
- The same physiological waveforms are displayed (ECG, respiration rate, IBP, Mean IBP, Pleth, CO_2, Temperatures) using the same software algorithms
- Interface to drug-to-drug and allergy-to-drug interaction database
- Configurable reports
- Inventory management
- Registry data collection and export

The technological differences between the subject and predicate devices are listed:

- The personal computer hardware used in the cath lab (Procedure Room and Control Room) are medical grade All-in-One integrated PC/display monitors or medical grade terminals with widescreen displays and antimicrobial housings
- A new model of the PDM from the same manufacturer (Schiller AG) is integrated: Argus PB-3000 (510(k) K221056)
- Visual technical and user-customizable visual alarms are added
- Temperature signals acquired by esophageal temperature probes are added
- The Merge Hemo software is updated to a new version 11 to accommodate interfaces with the updated hardware components
- Computer operating systems and SOUP are updated to current versions
- There is no enclosure for the Merge Hemo Record Station because there are no tower PCs to house

VII. Performance Data

The following non-clinical performance data were provided in support of the substantial equivalence determination.

<u>Electrical safety and electromagnetic compatibility (EMC)</u>

Electrical safety and EMC tests were conducted on Merge Hemo, Model RCSV2 for the Record Station Workstation, Procedure Room Hemo Monitor, and Remote Operators Terminal (ROT) hardware configurations and associated components such as

uninterruptible power supplies and/or isolation transformers, KVM extenders and cables, the PB-3000 PDM, and Merge Hemo software. The system complies with the current editions of applicable standards.

Electrical Safety

FDA Recognition Number	Title of Standard
19-49	IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

Electromagnetic Compatibility

FDA Recognition Number	Title of Standard
19-36	IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

Particular and Additional Standards

FDA Recognition Number	Title of Standard
5-132	IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION - Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
5-131	IEC 60601-1-8 Edition 2.2 2020-07 CONSOLIDATED VERSION - 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
19-19	IEC TR 60601-4-2 Edition 1.0 2016-05 - Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems (considered during evaluation)
3-126	IEC 60601-2-27 Edition 3.0 2011-03 - Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment [Including: Corrigendum 1 (2012)]
3-123	IEC 80601-2-30 Edition 2.0 2018-03 - Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

FDA Recognition Number	Title of Standard
3-115	IEC 60601-2-34 Edition 3.0 2011-05 - Medical electrical equipment - Part 2-34: Particular requirements for the basic safety including essential performance of invasive blood pressure monitoring equipment
1-140	ISO 80601-2-55 Second edition 2018-02 - Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
6-421	ISO 80601-2-56 Second edition 2017-03 - Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. [Including: Amendment 1 (2018)].
1-139	ISO 80601-2-61 Second edition 2017-12 (Corrected version 2018-02) - Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
N/A	IEC 80601-2-49:2018 – Medical electrical equipment - Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment (as applicable to the system integrator)
5-129	IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION – Medical devices – Part 1: Application of usability engineering to medical devices
5-125	ISO 14971 Third Edition 2019-12 – Medical devices – Application of risk management to medical devices
5-134	ISO 15223-1 Fourth edition 2021-07 – Medical Devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements
N/A	CISPR 11:2015/A1:2016/A2:2019, Group 1, Class A – Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement
N/A	ISO 13485:2016 MDSAP – Medical Devices – Quality management systems. Requirements for regulatory purposes

Software Verification and Validation

Verification and validation testing performed on the Merge Hemo software application, including testing with defined hardware configurations, demonstrated that the software meets its design requirements, and no new issues of safety and effectiveness were discovered.

Formal software development processes that comply with the requirements of IEC 62304 for medical device software life cycles are followed.

Software Life Cycle Process

FDA Recognition Number	Title of Standard
13-79	IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION – Medical device software – Software life cycle processes

Clinical Studies

Clinical testing was not required to demonstrate the safety and effectiveness of Merge Hemo, Model RCSV2.

VIII. Conclusions

Comparison of the Intended Use / Indications for Use and the technological characteristics of the subject and predicate devices demonstrates that no new intended uses are created, and that modifications to the technology do not raise new issues of safety and effectiveness.

The results of safety and performance testing, software verification and validation, bench testing and usability testing established that the subject device meets its design and performance specifications, and no new issues of safety and effectiveness were identified.

Therefore, Merge Hemo, Model RCSV2 is substantially equivalent to the legally marketed predicate device.