



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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April 7, 2016

Merge Healthcare Incorporated
Carol Nakagawa
Director, Quality And Regulatory Affairs
6303 Airport Road, Suite 500
Mississauga, L4V1R8 CA

Re: K152864

Trade/Device Name: Merge Hemo
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: March 2, 2016
Received: March 4, 2016

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 (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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

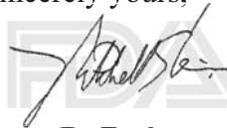
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K152864

Device Name

Merge Hemo

Indications for Use (Describe)

Merge Hemo displays, measures, and records physiological data from a patient undergoing a cardiac catheterization procedure.

The Hemo System can visualize and capture vital sign values including ECG, impedance respiration, SpO2 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 diagnostic quality 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 (EtCO2) along with apnea and respiration rates calculated from the EtCO2 waveform.

The hemodynamic portion of the system is comprised of the Patient Data Module (PDM) and the Merge Hemo Monitor PC. The two units are connected via a serial interface.

All vital parameters are acquired and calculated in the PDM. This data is then transmitted to the Merge Hemo Monitor PC via the serial interface. All data can then be displayed on the Merge Hemo Monitor PC. The Merge Hemo system is not intended to produce alarms for out-of-range conditions.

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 system is intended for use in hospital cardiac catheterization laboratories and in pre-and post-procedure care areas in the hospital under the close supervision of qualified medical personnel.

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

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Date Prepared: April 1, 2016

II. DEVICE

Name of Device: Merge Hemo™
Common or Usual Name: Hemodynamic Recording and Display System
Classification Name: Programmable Diagnostic Computer (21 CFR 870.1425)
Regulatory Class: II
Product Code: DQK

III. PREDICATE DEVICE

GE Mac-Lab, CardioLab, ComboLab, SpecialsLab v6.9.5, K130626 (primary predicate)
HeartSuite Hemodynamics, K082421

IV. DEVICE DESCRIPTION

Merge Hemo is a hemodynamic recording and display system designed to measure, record, and display vitals signs data for patients undergoing cardiac catheterization procedures.

The addition of a Merge Hemo software feature that provides the ability to calculate and display Fractional Flow Reserve (FFR) values is described. No hardware changes are required in order to enable or perform this functionality.

FFR provides a quantitative assessment of the functional severity of a coronary artery stenosis identified during coronary angiography and cardiac catheterization.

FFR measurement involves determining the ratio between the maximum achievable blood flow in a diseased coronary artery and the theoretical maximum flow in a normal coronary artery.

The Merge Hemo software user interface displays the pressure waveforms from the third party FFR pressure transducers that are placed distal and proximal to the lesion. When the FFR feature is enabled, the system shows the section of each of the waveforms that is used to calculate the mean pressure.

The results of the pressure waveform recording is expressed as a fraction of the normal blood flow in the coronary artery compared to the maximum achievable blood flow in the same artery. An FFR measurement of 1.0 indicates an artery with normal blood flow. FFR measurements less than 0.80 indicate that ischemia could be caused by blood flow blockage.

The Merge Hemo software initially selects segments of the waveforms to use for FFR calculations but the user can easily change where the values are taken by using the touchscreen interface to move the segment markers along the waveforms. The FFR value recalculates accordingly.

V. INTENDED USE

Merge Hemo displays, measures, and records physiological data from a patient undergoing a cardiac catheterization procedure.

The Hemo System can visualize and capture vital sign values including ECG, impedance respiration, SpO2 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 diagnostic quality 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 (EtCO2) along with apnea and respiration rates calculated from the EtCO2 waveform.

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VI. COMPARISON WITH PREDICATE

Merge Hemo and the primary predicate device GE Mac-Lab are hemodynamic recording and display systems that are capable of performing Fractional Flow Reserve (FFR) calculations. The calculation of the FFR ratio is relatively simple and is well known, based on blood pressure measurement values generated by third party FFR wires and transducers. There should be no significant differences in how Merge Hemo and the predicate device calculate the FFR value.

VII. NON-CLINICAL TESTS

Physiologic Simulator Test

In-house bench testing was performed using physiologic simulators, varying the input pressure values and checking the calculations generated by Merge Hemo for each set of simulated distal and proximal pressures.

Integration Test: Comparison of Merge Hemo System vs. ACIST FFR System

In-house bench testing was performed to support the validation of the FFR calculation, equivalency testing against FFR systems, and integration/compatibility testing with commercially available third party FFR pressure measurement devices that provide blood pressure data as inputs for the FFR calculation.

The FFR results calculated by Merge Hemo were compared with the FFR results calculated by an FDA 510(k) cleared (K132474) FFR system used under the same conditions: ACIST RXi Rapid Exchange FFR System by ACIST Medical Systems. The ACIST Navvus MicroCatheter fiber optic pressure transducer was used in both systems to measure the distal pressure. Both systems used the same standard pressure transducer to measure the proximal pressure. The Merge Hemo and ACIST FFR systems showed excellent correlation and met all criteria for accuracy and precision. The FFR calculations from both systems were demonstrated to be equivalent.

Integration Test: Compatibility of Different FFR Pressure Transducers

Several makes and models of FDA 510(k) cleared FFR pressure transducer devices and standard blood pressure transducers were tested in various combinations with the Merge Hemo system.

The statistical analysis of the data demonstrated that various makes and models of FFR pressure transducers are compatible with Merge Hemo, including:

- ACIST Navvus MicroCatheter
- St Jude Aeris PressureWire
- Volcano Verrata Pressure Guide Wire
- Volcano PrimeWire PRESTIGE® PLUS Pressure Guide Wire

The statistical analysis of the data also demonstrated that various makes and models of standard pressure transducers are compatible with Merge Hemo, including:

- Edwards TruWave Disposable Pressure Transducer
- ICU Medical Transpac IV Disposable Pressure Transducer System
- Merit Meritrans® Pressure Transducer

FFR tests were performed without manipulating or correcting the input pressure data or the FFR ratio calculations. The standardized pressure values generated by FFR transducers are consistent and compatible with Merge Hemo's FFR calculations.

All in-house bench tests passed. No issues of safety and effectiveness were raised.

No clinical tests were required in order to demonstrate the proper integration of the measurements into Merge Hemo for the calculation of FFR values.