510(k) Summary K082421 DEC 17 2008

Date Prepared: June 27, 2008

Contact Person: Inger Hanson
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Management Representative, CPO
Emageon, Inc.
Phone: 262-369-3379
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Device Trade Name: HeartSuite Hemodynamics

Common Name: Programmable Diagnostic Computer

Classification Name: 21 CFR 870.1425, Cardiovascular

Predicate Substantially Equivalent Devices: GE Mac-Lab (K061741)

Device Description: HeartSuite Hemodynamics monitors, measures, and records physiologic data from a human patient undergoing a cardiac catheterization procedure.

The Monitoring System is for the monitoring of vital parameters including ECG, SpO2, invasive blood pressure, temperature, NIBP and CO2, and for the evaluation of resting ECG, arrhythmias, ST-segments and cardiac output. Some systems are built and designed to measure End Tidal CO2.

The system comprises the Patient Data Module and the HeartSuite Hemodynamics Hemo Monitor PC. The two units are connected via a serial interface.

All vital parameters and evaluations are registered and calculated in the Patient Data Module. This data is then transmitted to the HeartSuite Hemodynamics Hemo Monitor PC via the serial interface. All data can be shown and monitored on the HeartSuite Hemodynamics Hemo Monitor PC.

The Patient Data Module uses an internal battery charged from an external power input (RS 232/12V). The power supply, like the data transmission, is completely isolated from the visualization unit. The HeartSuite Hemodynamics Hemo Monitor PC is powered via the normal mains connection 230V/110V.

The system is intended for use in hospital cardiac catheterization laboratories.

The Monitoring System (comprising the Patient Data Module and the HeartSuite Hemodynamics Hemo Monitor PC) is a medical product of the Class IIa (RL 93/42/EWG, Appendix IX).

Intended Use: HeartSuite Hemodynamics monitors, measures, and records physiologic data from a human patient undergoing a cardiac catheterization procedure.

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Performance Data: In order to ensure that the HeartSuite Hemodynamics software performs safely and efficiently, the HeartSuite Hemodynamics software was tested using physiologic simulators. Various types of ECG aberrations, rates, amplitudes, and deviations were used for validation of R-Wave detection for the rate meter and timing measurements related to pressure analysis. Multiple pressures were simulated under various conditions to validate the pressure and valve analyses. Multiple oxygen saturations were entered to validate hemodynamic calculations. End tidal CO2 was validated through Schiller and verified through tests run using SimMan. Multiple erroneous and/or incongruous entries were made in data entry locations to validate data entry restrictions. Multiple cases were created and exported to validate data integrity. All command buttons were tested for their appropriate responses. Multiple reports were generated to validate the report generation functions. The software responded appropriately in the tests described. After assembly is completed each unit undergoes final products testing. Patient isolation and leakage current tests are to be performed on each unit prior to packaging for shipment.

In addition to functional testing, a risk analysis, requirements review and design review was performed.

No clinical performance data has been used to support the substantial equivalence claim.

Substantial equivalence summary: The Emageon HeartSuite Hemodynamics system is a comparable type and substantially equivalent to a legally marketed predicate device. The intended use of the Emageon HeartSuite Hemodynamics system is the same as that of the predicate device Mac-Lab, marketed by GE Healthcare. No new safety or effectiveness issues are raised with the Emageon HeartSuite Hemodynamics system. The subject device has substantially equivalent technological characteristics, features, specifications, materials, modes of operation and intended uses as a legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2008

Emageon, Inc.
c/o Mr. Mark Job
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 53313

Re: K082421
Trade/Device Name: HeartSuite Hemodynamics
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II (Two)
Product Code: DQK
Dated: November 25, 2008
Received: November 28, 2008

Dear Mr. Job:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

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): K082421

Device Name: HeartSuite Hemodynamics

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

for Bzuckerman

(Division Sign-Off) 12/14/08

Division of Cardiovascular Devices

510(k) Number K082421