HEMA METRICS™

K093834

SEP 29 2010

510(k) Summary

As Required by 21 CFR 807.92

510(k) Number: _____

1. Submitter Information

Submitter Name: Hema Metrics, LLC
695 North 900 West
Kaysville, UT 84037-4118
Tel: 801-451-9000
Fax: 801-451-9007

Establishment Reg.: 1721979

Contact Person: Douglas L. Cox
Director of Quality Assurance/Regulatory Affairs

Date Prepared: June 24, 2010

2. Device Information

Trade Name: Crit Line Anemia Management (CLAM)

Classification Name: Hemodialysis system monitor accessory

Product Code: MSQ, JQP

Classification Reg. 876.5820, 862.2100

Class: Class II

3. Predicate Device Information

Predicate 1 - Crit Line

Trade Name	Crit Line III_{TQA} Access Management
Common Name	Non-invasive Hematocrit, Blood Volume, Oxygen Saturation, Recirculation and Access Blood Flow
Classification Name	Crit Line Monitor III with TQA (CLM III_{TQA})
510(k)	K001763
Classification Regulations	876.5820
Product Code	MQS

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Predicate 2 - Vasc-Alert

Trade Name	Vasc-Alert
Common Name	Hemodialysis access site patency monitoring software
Classification Name	System, hemodialysis, Access Recirculation Monitoring
510(k)	K042566
Classification Regulations	876.5820
Product Code	MQS

4. Intended Use

The CLAM software is a database application used to record, track and trend patient data pertaining to the management of anemia, and to provide a dosage recommendation. The CLAM software is intended to manage anemia in adult end stage renal failure patients.

5. CLAM Software Description

The CLAM software is a database application that records, tracks, trends, and analyzes patient data (Hematocrit, Oxygen Saturation, and Hemoglobin) along with current ESA dose in order to effectively manage anemia.

During dialysis treatment, the CLAM downloads initial, real-time Hematocrit (HCT), Oxygen Saturation (SaO2), and Hemoglobin (Hb) data from the Crit Line blood monitor. The CLAM software trends this patient data along with current Erythropoiesis Stimulating Agent (ESA) dosage to determine the patient's Hb levels, the need (if any) for ESA dosing, and to track patient's response to treatment. The CLAM software uses a proprietary algorithm to calculate a recommendation for ESA dosage based on patient data trends and current ESA dose in order to establish and maintain predetermined patient Hb levels. The The CLAM proprietary algorithm used to determine ESA dosing for anemia treatment is based on the current manual algorithm. In addition, the CLAM software generates and prints patient reports for review and record keeping.

The CLAM software resides on a host computer separate from the Crit Line units and acquires real-time data from the clinic's Crit Line monitors via wireless radio signal or by a serial cable.

A. Crit Line IIITQA Blood Volume Monitor and CLAM Accessory

The Crit Line uses optical methods to measure HCT, SaO2, and then calculates Hb from HCT for patients undergoing hemodialysis treatment. The Crit Line system consists of a blood monitor, optical clip and blood chamber.

The blood chamber is attached to the dialysis tubing prior to treatment and the optical clip is clipped to the blood chamber, allowing optical access to the blood flow. The Crit Line monitor collects baseline (pre-treatment) readings of HCT, SaO2, and Hb levels and subsequent ongoing readings during treatment. When Crit Line units are used with the CLAM software accessory, baseline readings are transferred to the CLAM application, which establishes a baseline and subsequently performs near real-time monitoring as described above.

B. Intended Patient Population

The CLAM software currently is intended for use in dialysis clinics which care for adult renal failure patients :(see Section 21 – Other for the study: "Use of 12x/month haemoglobin monitoring with a computer algorithm reduces haemoglobin variability").

C. Intended User Population and Use Environment

The CLAM software is intended for use by medical personnel such as clinicians, nurses, and physicians in dialysis clinics or where ever dialysis treatment is provided and/or Crit Line is used.

D. CLAM Software User Interface

The CLAM software interface is designed to centralize and automate many of the routine tasks performed by medical staff when collecting and handling patient data used in the management of anemia. Features of the CLAM software enables the user to collect, record, track, trend, report, analyze, and print data for review and record keeping. An additional feature of the CLAM software is the ability to calculate a recommended ESA dosage based on trending of patient Hb and current ESA dose.

6. Technological Comparisons

A. Similarities to Predicate Devices 1 & 2

- The CLAM software, Crit Line (predicate 1), and Vasc-Alert (predicate 2) devices provide a (pre-treatment) baseline of patient HCT readings.
- The CLAM software and predicate 2 devices are software database applications designed to record, track, trend patient data.
- The CLAM software and Vasc-Alert software device perform trend analysis on patient data routinely collected during dialysis treatment
- All three allow the medical staff to set thresholds or limits for each patient, which when not met signal an alert.
- All three enable medical staff to record and track patient data with each dialysis treatment providing continual monitoring of patient status verses the standard once a month measurement protocol.
- All three devices are intended to be a reference for patient status and when considering course of treatment. For comparison of each predicate to new device see, Table 1 Similarities and Table 2 Similarities:

SIMILARITIES to CRIT LINE (predicate 1)		
Item	**New Device**	**Predicate Device**
Indication for Use	Management of Hematocrit based Hemoglobin levels in dialysis patients	Same
Principle of Operation	Non-invasive means of recording and tracking patient data: Hematocrit, Hemoglobin, Oxygen Saturation which can be used to determine the need and/or course of treatment.	Same
Technology	Algorithm used to trend patient data collected during each dialysis treatment.	Same
Patient Demographics	Dialysis & CRRT patients	Same
Intended User	Physician/Clinicians/Nurses	Same
Data Storage	Data is stored on computer media or network	Same
Data Management	Reports and graphs are available for view or print	Same
Manual Data Entry	GUI interface allows for patient data to be entered and edited manually.	Same
Safeguards/Alerts	System flags patients whose Hematocrit based Hemoglobin levels fall outside set limits.	Same

Table 1 - Similarities

SIMILARITIES to Vasc-Alert (predicate 2)		
Item	**New Device**	**Predicate Device**
Principle of Operation	Software database application which records, tracks and trends patient data used as a reference when determining treatment.	Same
Data Analysis	Trends and analyses patient data and sets thresholds or limits	Same
Technology	Algorithm used record, track, and establish a baseline of patient data collected during initial phase of dialysis treatment	Same
Patient Demographics	Dialysis & CRRT patients	Same
Intended User	Physician/Clinicians/Nurses	Same
Data Storage	Data is stored on computer media or on a network	Same
Data Management	Reports and graphs are available for view or print	Same
Manual Data Entry	GUI interface allows for patient data to be entered and edited manually via keyboard and/or mouse interface.	Same
Safeguards/Alerts	System flags patients who exceed set limits.	Same

Table 2 - Similarities

B. Differences

Differences between the CLAM software and predicate devices 1 & 2:

- The CLAM software offers an ESA dosage recommendation based on trending of patient's hematocrit based hemoglobin levels and the current ESA dose.
- The CLAM software algorithm is for the purpose of managing anemia following hemodialysis therapy, refer to Table 3 Differences and Table 4 Differences below:

DIFFERENCES - CRIT LINE (predicate 1)		
Item	**New Device**	**Predicate Device**
Technology /Algorithm	Algorithm used to trend Hb levels and current ESA dose and based on trending of data calculate a recommended ESA dosage	Algorithm used to plot HCT, SaO2, and Hb data and report results in real time
Data Analysis	Provides an improved recommended ESA dosage based on significantly more data points than current once per month laboratory blood draws therefore trending of historical patient Hemoglobin levels and ESA dosage keeps ESA dosing in better compliance to ESA instructions	Provides results of collected and analyzed data only
Hardware	CLAM is a software database which resides on a host computer and communicates with Crit Line monitor via radio and/or serial link	CLM III Monitor is a stand alone device which communicates with CLAM via radio and/or serial link

Table 3 Differences

DIFFERENCES – VASC-ALERT (predicate 2)		
Item	**New Device**	**Predicate Device**
Indication for Use	Management of Hematocrit based Hemoglobin levels in dialysis patients	Monitors access flow patency of fistulas and grafts in hemodialysis patients
Technology /Algorithm	Algorithm used to trend Hb levels and current ESA dose and based on trending of data calculate a recommended ESA dosage	VAPR algorithm used to trend hematocrit and pressure flow rate to determine access flow rate.
Data Analysis	Provides an improved recommended ESA dosage based on significantly more data points than current once per month laboratory blood draws therefore trending of historical patient Hemoglobin levels and ESA dosage keeps ESA dosing in better compliance to ESA instructions	Places patient on report for referral to an interventionalist.

Table 4 Differences

C. Performance Data

A performance test was completed in September of 2009 at a dialysis center in New England where the CLAM software ESA dosage calculations were compared to ESA dosage calculations performed manually.

The test consisted of taking data from sixty-two dialysis patients for analysis. The last two weeks of a patient's Hb values were recorded and the average of Week 1 was subtracted from the average of Week 2. If the difference between the two weeks is positive then the trend is falling, and if the difference was negative the trend was rising. The average of Week 1, the absolute value of the difference, and the rising or falling trend is then used to derive the next recommended dose. The results showed that the CLAM software calculated recommended dose and the manually calculated dose were exactly the same.

D. Conclusion

The CLAM software is designed to work in tandem with the predicate device (Crit Line) to provide a more comprehensive and accurate approach to managing anemia treatment following hemodialysis.

The Crit Line uses an optical method to measure HCT and SaO2 and then calculate Hb from HCT for patients undergoing hemodialysis. Crit Line takes a baseline reading just prior to the start of hemodialysis and then continues to take measurements during the duration of treatment. Upon completion of the hemodialysis run the CLAM software downloads these baseline readings to the CLAM database where it is stored for tracking and trending.

The current protocol used by most clinics to assess Hb levels in a dialysis patient is to draw blood one time per month from which the physician prescribes (if needed) ESA dosage for the following month or until the next blood draw. This method provides little data and does not account for the time and changes experienced by the patient between blood draws. One change experienced by the patient is the removal of excess fluid during hemodialysis. On average a dialysis patient will undergo ten to twelve dialysis treatments between the once a month blood draw. The changes to HCT in relation to total blood volume are changed with each hemodialysis treatment affecting Hb levels as well.

The CLAM software provides the means to record, track, and trend these critical changes along with current ESA dose with each hemodialysis treatment. This method provides up to twelve points of data per month to measure patient status compared to the one point currently used. Based on trending of Hb levels and current ESA dose the CLAM software gives an ESA dosage recommendation for the physician's consideration.

The CLAM software device, like the Crit Line monitor, is for use only under supervision of a healthcare provider and is not intended to replace the knowledge and experience of the healthcare provider when prescribing treatment.

Additional safeguards are incorporated in the CLAM software interface and algorithm to mitigate or prevent harm to the patient by limiting the maximum dosage recommendation of the CLAM software to 20,000 IU per treatment, to flag those patients whose Hb levels fall outside the established limits, and to prevent interchange of Hb and HCT values when entered manually.

In conclusion, the CLAM software like the predicate devices is designed to record, track, and trend patient data for the purpose of providing accurate readings, ongoing analyses of patient data, and as a reference for physicians when determining an effective course of treatment. For these reasons the CLAM software is considered equivalent to the predicate devices and does not pose any additional safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Hema Metrics, LLC
C/O Mr. Terry Lanier
136 W. 2nd Street
Ogden, Utah 84404

SEP 29 2010

Re: K093834
Trade/Device Name: Crit-Line Anemia Management Software
Regulation Number: 21 CFR 876.5820
Regulation Name: Hemodialysis System Monitor Accessory
Regulatory Class: II
Product Code: MSQ, JQP
Dated: September 13, 2010
Received: September 15, 2010

Dear Mr. Lanier:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

HEMA METRICS™

Indication for Use Statement

K093834

SEP 29 2010

510(k) Number: _____

Device Name: Crit-Line Anemia Management Software

Indications for Use: The Crit-Line Anemia Management software is a database application used to record, track and trend patient data as pertains to the management of anemia, and provide a dosage recommendation.

Prescription Use_ _X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman 9/27/10

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K093834