JUL 2 3 2002

510 (K) Summary (#K011741) – Updated July 22, 2002

SECTION 1 – GENERAL INFORMATION

1. **Applicant/Specification Developer:**

HemaMetrics
695 North 900 West
Kaysville, UT 84037
Tel: (801) 451-9000
Fax: (801) 451-9007

Registration Number: 1721979

2. **Contact Persons:**

Mr. Matthew L. Haynie
Dir. of Quality Assurance/Reg. Affairs

3. **Administrative Information:**

a. Trade/Proprietary Name Including Model Number of Devices:

CRIT-LINE III TQA Monitor (CLM III TQA)

b. Common Name or Classification Name (21 CFR Part 807.87) of Device:

Non-invasive Hematocrit, Blood Volume, Oxygen Saturation, Recirculation and Access Blood Flow Monitor

c. Address of Manufacturing Facility/Sterilization Sites:

HemaMetrics
695 North 900 West
Kaysville, UT 84037

Contract Manufacturers:

None

The CLM III TQA is a non-sterile product.

d. Class in which Device has been placed:

Class II

e. Reason for Pre-market Notification

The reason for this pre-market notification is to claim that the CLM III TQA can non-invasively measure the Urea Reduction Ratio based on detected changes in the urea nitrogen concentration in the spent dialysate. The URR is a key indicator as to the efficiency of a hemodialysis treatment. It indicates the extent of toxin urea removal from the patient's body as a result of the blood flowing across one side of the dialyzer with continuous counter-flow of dialysate on the opposite side of the dialyzer membrane.

NOTE: The CLM III TQA is already cleared for the non-invasive measurement of Hct, O2 Sat, and Percent Change in Blood Volume. In addition, the CLM III TQA estimates access recirculation and transcutaneously estimates Access Blood Flow. URR is an additional claim for this already cleared device.

f. Identification of Legally Marketed Device Which We Claim Substantial Equivalency

The predicate method which was used to compare the urea nitrogen concentration measurements of the CLM III TQA includes the following:

EktaChem DT60 (*Vitros* DT60 Chemistry System):

The DT60 is a *Vitros* DT slide analyzer that performs a number of discrete clinical tests on serum, plasma, or whole blood using optical density techniques. Each *Vitros* DT slide, therefore contains analyte-specific reaction reagents whose resulting product is a molecule with a given color. The amount of colored product or the optical density is therefore directly dependent on the original analyte concentration delivered onto the *Vitros* DT slide. Optical density measurements are performed with a fiber optic-based excitation and detection scheme employing one of three LED's (red, green, yellow) and one photodetector.

***Vitros* DT Slide Characteristics Specific for BUN/UREA:**
The BUN/ UREA DT slide is a multilayered dry film contained within a plastic support. All reagents specific to urea are self-contained within the slide. Color development results from the hydrolysis of urea to ammonia and carbon dioxide by the urease enzyme. The resulting ammonia subsequently reacts with an indicator to produce a highly colored dye.

g. Compliance with Requirements of the Federal FD&C Act:

The Gastrointestinal and Restorative Device (DGRD) Panel has classified this device as Class II, 21 CFR Part 876.5820

SECTION 2 – INTENDED USE

The intended use of the CRIT-LINE III TQA Monitor is as a non-invasive hematocrit, oxygen saturation, and percent change in blood volume monitor. The CRIT-LINE III TQA Monitor also non-invasively estimates access recirculation and non-invasively estimates access blood flow. In addition, the CLM III TQA Monitor calculates an estimated Urea Reduction Ratio based on relative changes in urea nitrogen concentration in the spent dialysate.

SECTION 3 – DEVICE DESCRIPTION

The CRIT-LINE III TQA is an FDA cleared device that non-invasively measures Hct, O2 Sat, Percent Change in Blood Volume. The CLM III TQA also estimates Access Recirculation and Access Blood Flow. The URR sensor is an additional attachment to the CRIT-LINE III TQA. The optical light emitted by the URR sensor is directed through the spent dialysate stream and absorbed by the constituents of the spent dialysate. The transmitted light is then detected and the relative urea nitrogen concentration in the spent dialysate is calculated.

SECTION 4 – COMPARATIVE INFORMATION

a. Comparative Performance Evaluation:

IN-VIVO UREA NITROGEN DETECTION

Between January 1 and May 10, 2001, 51 data points were gathered in-vivo on 36 patients comparing the CLM III TQA's calculated URR based on relative urea nitrogen concentration measurements in the spent dialysate to URR measurements as calculated by the EktaChem DT 60 based on urea nitrogen concentration measurements in both blood and spent dialysate.

Once the data was gathered, an analysis of the data was performed. Relative urea nitrogen concentrations measured by the CLM III TQA URR sensor were first compared with that measured by the EktaChem DT 60. The analysis yielded a standard error of 5.8 mg/dL and an R of 0.84. Since each patient run has its own characteristics which can be cancelled through the ratio during the URR calculation, the accuracy of this comparison is not affecting the accuracy of calculated URR.

IN-VITRO UREA NITROGEN CALIBRATION:

In addition to the in-vivo data that was gathered from the patients in a clinical setting, the same optical-based CLM III TQA URR sensor as mentioned above was calibrated with pure urea dissolved in fresh dialysate solution. The URR sensor measurement at each urea nitrogen concentration was compared with the

reference urea nitrogen concentration measured by a Kodak EktaChem DT 60 analyzer.

In the urea nitrogen concentration range of 0 ~ 83 mg/dL, the CLM III TQA URR sensor measurements had a standard error of 1.2 mg/dL and an R^2 of 0.998 when compared to the reference measurements obtained from EktaChem DT 60. These results indicate that the CLM III TQA URR sensor and the Kodak EktaChem DT 60 analyzer are substantially equivalent in the measurement of urea nitrogen concentration in an in-vitro assay.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 3 2002

Mr. Matthew L. Haynie
Director of Quality Assurance/
Regulatory Affairs
HemaMetrics™
695 North 900 West
KAYSVILLE UT 84037

Re: K011741
Trade/Device Name: CRIT-LINE III TQA URR Monitor
Regulation Number: 21 CFR 876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: 78 FIL and 78 MQS
Dated: April 20, 2002
Received: April 24, 2002

Dear Mr. Haynie:

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 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 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 Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K011741

Device Name: CRIT-LINE III TQA MONITOR

Indications for Use:

The intended use of the CRIT-LINE III TQA Monitor is as a non-invasive hematocrit, oxygen saturation, and percent change in blood volume monitor. The CRIT-LINE III TQA Monitor also non-invasively estimates access recirculation and non-invasively estimates access blood flow. In addition, the CLM III TQA Monitor calculates an estimated Urea Reduction Ratio based on relative changes in urea nitrogen concentration in the spent dialysate.

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K011741

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription for Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)