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K972470

DEC 1 1 1997

510(k) SUMMARY

1. **Submitter's Information:**

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In-Line Diagnostics
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510(k) Summary Prepared by:

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2. **Date 510(k) Summary Prepared:** June 27, 1997

3. **Name of the Device**

Trade or Proprietary Name: CRIT-LINE Monitor III (CLMIII)

Common Name: Non-invasive hematocrit, blood volume and oxygen saturation monitor

Classification Name: Hemodialysis system monitor accessory

4. **Identification of legally marketed device which the submitter claims equivalence.**

The CRIT-LINE III (CLMIII) is substantially equivalent to the CRIT-LINE II (CLMII) currently marketed by In-Line Diagnostics in significant features, materials, dimensions and intended use..

5. Description of the Subject Devices:

The CLMIII consists of a state-of-the-art microprocessor which has all of the chip select logic, serial communication, timing and watchdog circuits incorporated within it. The CLMIII is used in conjunction with the In-Line Diagnostics, Inc. Blood Chamber. The Blood Chamber is connected to and becomes part of the dialysis tubing circuit. The sensor from the CLM is connected to the Blood Chamber which reads critical blood parameters as the blood passes through the Blood Chamber

6. Intended Use of the Subject Devices:

The CLMIII and the predicate CLMII are used as non-invasive hematocrit, oxygen saturation and blood volume monitors. Both measure hematocrit, percent change in blood volume and oxygen saturation in real time for application in the treatment of dialysis patients with the intended purpose of providing a more effective treatment for the dialysis patient. Based on the data that the monitors provide, the dialysis technician increases or decreases the rate at which fluid is removed from the blood in order to remove the maximum amount of fluid from the dialysis patient without the patient experiencing the common symptoms of dialysis which include nausea, cramping and vomiting.

7. Technological Characteristics of the Subject Devices.

Both the predicate CLMII and the CLMIII are identical in function and operate under the principles of light absorption through the blood under test to measure oxygen saturation (O_2 SAT) and hematocrit (HCT) and to calculate the related value of Blood Volume (BV).

The CLMIII uses a Motorola 61332A microprocessor which is also a member of the Motorola 68000 family of microprocessors used in the CLMII, but is more up-to-date and has incorporated within it all of the chip select logic, serial communications, timing and watchdog circuits. The code was consolidated into a more modular version to parallel the hardware layout. The measurements in both the CLMII and the CLMIII are accomplished by calibrated Analog to Digital Converters (ADC). The CLMII uses a multiplexer to switch between two circuits, whereas the CLMIII contains completely separate circuits.

8. Discussion of Clinical Tests Performed:

No Clinical testing was performed. Comparison testing to the predicate was performed on blood bank blood under simulated clinical conditions at In-Line Diagnostics, Inc.

9. Conclusions:

In summary, based on comparison with the legally marketed CLMII and tests of this device to IEC 601-1: 1988 and to the FDA Guidance for Premarket Notification Submission Appendix A Sections (ii) (a) and (ii) (b) for Electrostatic Discharge and Electromagetic Interference (EMI), the subject CLMIII is safe and effective and performs as well as the legally marketed CLMII.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 11 1997

Mr. Matthew L. Haynie
Director of Quality Assurance
In-Line Diagnostics Corporation
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Suite 160
Riverdale, Utah 84405

K972470
In-Line Diagnostics CRIT-LINE Monitor III
(for Hemodialysis Applications)
Dated: October 8, 1997
Received: October 10, 1997
Regulatory Class: II
21 CFR §876.5820/Product Code: 78 MQS

Dear Mr. Haynie:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

William Yin

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

EXHIBIT A

510(k) Number (if known): K972470

Device Name: CRIT-LINE Monitor III (CLM III)

Indications for Use:

The family of CRIT-LINE Monitors (CLM's), include the CLM II (predicate device) and the CLM III. These devices are used to non-invasively to measure hematocrit, oxygen saturation and percent charge in blood volume. Both the CLM II and the CLM III measure hematocrit, percent change in blood volume and oxygen saturation in real time for application in the treatment of dialysis patients with the intended purpose of providing a more effective treatment for both the dialysis patient and the dialysis technician. In addition, the CLM II and CLM III estimate the amount of blood that is recirculated back into the dialysis circuit instead of the patients circulating volume. Based on the data that the monitors provide, the dialysis technician intervenes (i.e. increases or decreases the rate at which fluid is removed from the blood) in order to remove the maximum amount of fluid from the dialysis patient without the patient experiencing the common symptoms of dialysis which include nausea, cramping and vomiting.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R Saalfeld

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K972470

Prescription Use ✓ OR Over-The-Counter Use ___
(PER21 CFR 801.109

(Optional Format 1-2-96)