



510(k) SUMMARY

1. Submitter's Information

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510(k) Summary Prepared By:

Same as above

2. Date 510(k) Summary Prepared:

July 7, 1998

3. Name of Device:

CRIT-LINE MONITOR III (CLM III): Permission to claim additional feature of Access Blood Flow (ABF).

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 ABF values, which have been calculated from of the hematocrit data measured by the CLM III, have been found to be substantially equivalent to the values measured by the Transonic HD01 Monitor (#K960817) which is currently being marketed by Transonic Systems, Inc.

5. Description of the Subject Devices:

The CLM III 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 CLM III is used in conjunction with the In-Line Diagnostics Blood Chamber. The blood chamber is connected to and becomes part of the dialysis tubing circuit. The sensor from the CLM III is connected to the blood chamber which reads critical blood parameters as blood passes through the blood chamber.

6. Intended use of the Subject Device:

The CLM III is used as a non-invasive hematocrit, oxygen saturation and blood volume monitor. These parameters are measured 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 and decreases the rate at which fluid is removed from the patient's blood in order to maximize fluid removal without the patient experiencing the common symptoms of dialysis which include nausea, cramping and vomiting.

Recently, it has come to the attention of In-Line Diagnostics (IDC), that the CLM III can also be used to measure Access Blood Flow (ABF) which is the rate at which blood is flowing through the dialysis patient's access site. *This measurement can be made without any software or hardware changes to the current device.* ABF is a good indicator of a site's condition (i.e. how deteriorated or blocked that site has become). Providing a quick easy method of determining ABF would eliminate the need for more expensive, time-consuming methods such as X-ray.

It is IDC's intention to show in this submission that the ABF values gathered by the CLM III technique are substantially equivalent to the values gathered by the Transonic HD01 Monitor and as a result be allowed to claim ABF as an additional feature to the CLM III.

7. Technological Characteristics of the Subject Devices:

As stated above, the CLM III can be used to measure ABF without any hardware or software changes. ABF values are calculated by an independent means (i.e. calculator or spreadsheet) from real time hematocrit measurements which are measured by the CLM III. As a result, the technological characteristics (both hardware and software) are exactly the same as in the previous submission of the CLM III (#K972470).

8. Discussion of Clinical Tests Performed:

The CLM III ABF values were compared to the Transonic HD01 ABF values during two separate studies in March and April 1998. One study took place on 30 patients at the University of Utah Dialysis Program and Veterans Hospital in Salt Lake City, Utah and the other study took place on 14 patients at Victoria Hospital South in London, Ontario Canada.

During the study, a formal protocol was followed in which hematocrit data was gathered during normal dialysis sessions. During the session, ultrafiltration rates were adjusted and the arterial and venous lines were temporarily reversed. During this time, hematocrit values were gathered at four-minute intervals. These hematocrit values were then calculated into a formula (i.e. with a calculator or spreadsheet) to calculate an AFB value. This ABF value was then compared to the Transonic HD01 ABF value which was measured at the conclusion of the four-minute measurements previously described.

When the CLM III ABF data was compared to the Transonic HD01 data, it was determined that the criteria for the CLM III values to be considered as substantially equivalent was a correlation coefficient value near 1 (i.e. .90 or greater).

The results from the two tests indicate that the above described criteria were met.

9. Conclusions

In conclusion, based on comparison with the legally marketed Transonic HD01 Monitor, the subject CLM III is safe and effective and performs as well as the legally marketed Transonic HD01 Monitor.

OCT - 9 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Matthew L. Haynie
Director of Quality Assurance/Regulatory Affairs
In-Line Diagnostics Corporation
117 West 200 South
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Re: K982412
CRIT-LINE III Monitor
(for Access Blood Flow in Hemodialysis)
Dated: July 7, 1998
Received: July 13, 1998
Regulatory Class: II
21 CFR 876.5820/Procode: 78 MQS

Dear Mr. Haynie:

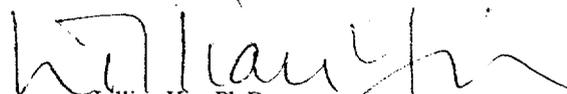
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 requirements, 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/dsma/dsmamain.html>".

Sincerely yours,



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

510(k) Number (if known): K982412

Device Name: CRIT-LINE III MONITOR with additional feature – Estimation of Access Blood Flow

Indications for Use:

The CRIT-LINE MONITOR III, (CLM III), is a non-invasive hematocrit, oxygen saturation and percent change in blood volume monitor used in the treatment of hemodialysis patients. In addition, the CLM III estimates access recirculation and access blood flow in hemodialysis patients.

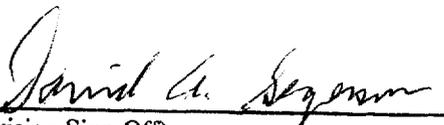
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription for Use _____
(Per 21 CFR 801.109)

OR

Over the Counter Use _____
(Optional Format 1-2-96)



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982412