K992227

JUL 30 1999

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— IN-LINE DIAGNOSTICS™ ————————————————

510(k) SUMMARY

1. Submitter's Information

Matthew L. Haynie
In-Line Diagnostics (IDC)
117 West 200 South
Farmington, UT 84025
Tel: 801-451-9000
Fax: 801-451-9007

510(k) Summary Prepared By:

Same as above

2. Date 510(k) Summary Prepared:

June 25th, 1999

3. Name of Device:

CRIT-LINE MONITOR III (CLM III)

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 were calculated by the CLM III have been compared to the approved method of ABF measurement where measured hematocrit values of the CLM III are gathered and calculated via an external source (i.e. calculator, spreadsheet, etc.) in order to obtain an Access Blood Flow value.

The 510 (k) # for the external source method of determining Access Blood Flow is K982412.

It is IDC's intention to show in this submission that the ABF values gathered by the CLM III are substantially equivalent to the values resulting from the already approved method of ABF determination using the CLM III and an external source (i.e. calculator, spreadsheet, etc.)

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 intended use of the CRIT-LINE III Monitor is as a non-invasive hematocrit, oxygen saturation and access blood flow-measuring device.

7. Technological Characteristics of the Subject Devices:

Since the CLM III has not changed in any way except for the software modification concerning the measurement of Access Blood flow, please refer to the original CLM III 510(k) submission for a complete device description (see #K972470).

8. Discussion of Clinical Tests Performed:

ABF measurements were validated by comparing statistical data between ABF values calculated internally by the CLM III and ABF values gathered by taking CLM III hematocrit measurements and placing these measurements into a formula where they could be calculated externally by a calculator or spreadsheet program.

Sixteen data points were taken on April 8th and April 9th, 1999 at Victoria Hospital in London Ontario Canada and an additional 13 data points were taken on June 22nd, and June 24th, 1999 at Central Valley Dialysis in Salt Lake City Utah.

A correlation coefficient statistically generated was used as the comparison criteria to evaluate the internally calculated CLM III ABF data against CLM III ABF data gathered via the external method. A coefficient value near 1 (i.e. .90 or greater) denotes a strong correlated relationship of the data. Twenty-nine data points were gathered with a resulting coefficient value of .94. The average difference between the two methods of ABF measurement was 46 ml/min with a standard deviation of 200 ml/min.

9. Conclusions

In conclusion, based on comparison with the legally marketed CLM III external method for Access Blood Flow Measurement, the subject CLM III is safe and effective for internal ABF measurement and performs as well as the legally marketed CLM III external method.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 1999

Mr. Matthew L. Haynie
Director of Quality Assurance/Regulatory Affairs
In-Line Diagnostics Corporation
117 West 200 South
P.O. Box 685
Farmington, UT 84025-0685

Re: K992227
CRIT-LINE III Monitor for Access Blood Flow
(Modification)
Dated: June 25, 1999
Received: July 2, 1999
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 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). 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,

CAPT Daniel G. Schultz, M.D.
Acting 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): K992227

Device Name: CRIT-LINE III MONITOR

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.

(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)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K992227