MAY 27 1999

K983551

510(k) SUMMARY

1. **Submitter's Information**

Matthew L. Haynie
In-Line Diagnostics (IDC)
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Farmington, UT 84025
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510(k) Summary Prepared By:

Same as above

2. **Date 510(k) Summary Prepared:**

September 28th, 1998 (updated May 25th, 1999 as per Dr. Charles C. Ho's suggestion)

3. **Name of Device:**

CRIT-SCAN II Monitor:

Common Name:

Non-invasive (transcutaneous) hematocrit monitor

Classification Name:

Physicians Office Lab/Blood Donor Facility Accessory

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

The CRIT-SCAN II is an improvement to its predecessor, the CRIT-SCAN, which received 510 (K) approval in April 1992 (see # K910077). In the CRIT-SCAN 510 (K) submission, IDC claimed an accuracy level of ± 3 HCT% as compared to the microcentrifugation method of hematocrit measurement. For the CRIT-SCAN II, IDC claims an accuracy level of 1.5 HCT% as compared to Coulter Counter method of hematocrit measurement.

NOTE: All data collected with the CRIT-SCAN II was compared to a Coulter Counter, a highly accepted method of hematocrit measurement in the blood processing industry. Due to the nature of the study, it made more sense to compare the CRIT-SCAN II to a Coulter Counter rather than its predicate device, the CRIT-SCAN. This is due to the time restraints of taking measurements from a majority of patients whose hematocrit was changing at a quick rate (i.e. dialysis patients).

5. Description of the Subject Devices:

The CRIT-SCAN II consists of state-of-the-art optoelectronics which, when combined with custom software, has the ability to measure hematocrit transcutaneously (i.e. through a patient's middle finger or index finger). The patient's finger is placed into a custom designed cuff which, when filled with air, creates the necessary perfusion for the optoelectronics to take a hematocrit reading.

6. Intended use of the Subject Device:

The intended use of the CRIT-SCAN II Monitor is as a continuous, non-invasive hematocrit-measuring device whereby a physician could use the information to determine the anemic state of the patient. A patient would place one of his or her fingers in a custom designed sensor assembly. In less than 30 seconds, the CRIT-SCAN II provides a hematocrit reading, thus providing the physician with an accurate value concerning the patient's anemic state.

Use of the CRIT-SCAN II would eliminate the need for a "finger stick", which is commonly used to get a sufficient sample of blood for hematocrit determination. Eliminating the need for a "finger stick" prevents all the potential problems associated with needles, communicable blood diseases and patient discomfort.

It is also anticipated that the CRIT-SCAN II would be beneficial in an intensive care environment where being able to non-invasively measure a patient's hematocrit within one minute could expedite proper treatment.

NOTE: The CRIT-SCAN II is not for pediatric use.

7. Technological Characteristics of the Subject Devices:

The CRIT-SCAN II is a non-invasive electromechanical/optical hematocrit-measuring device. The optical light emitted by the device is scattered by the blood and then detected the device. The hematocrit measurement is a function of how the light is absorbed and scattered.

8. Discussion of Clinical Tests Performed:

Between December 11th, 1997 and September 10th, 1998, IDC gathered data on 198 patients. The data was gathered during 9 separate studies conducted in the United States (8) and Sweden (1). All measurements taken with the CRIT-SCAN II were taken non-invasively and no intervention took place based on the readings of the CRIT-SCAN II. All subjects were required to complete a consent form since a blood sample was to be drawn. The following is a brief description of the method used to gather the data.

a. Once the subject's age, gender, pigmentation and finger size were recorded, the CRIT-SCAN II's measuring source was placed onto the subject's finger with the optoelectronics placed against the "fatty pad" or underside of the finger.

b. The instrument was turned ON and the quality of the optical and electrical signals was validated.

c. If the optical or electrical signal was insufficient (i.e. poor perfusion) the subject's hand (including the finger being measured) was rubbed or warmed to increase circulation.

d. Once the optical and electrical signals were validated, data was recorded by the CRIT-SCAN II Monitor while a blood sample was drawn either from the subject's arm or from the subjects dialysis circuit (if a dialysis patient).

e. The blood sample was immediately measured via a cell counter (Coulter Counter) as well as a hemoglobin measuring device and the data was recorded.

f. The data measured by the CRIT-SCAN II was compared to the corresponding cell counter data.

The following is a breakdown of the 198 subjects from which the data points were gathered:

a. Sex: Data was gathered on 105 males and 93 females. During the study, no hematocrit dependence was noted based on sex.

b. Age: The youngest subject tested was 17 years old while the oldest subject was 79 years old. IDC did not take any pediatric measurements or any measurements on subjects less than 17 years old. During the study, no hematocrit dependence was noted based on age.

c. Subject Condition: 74 subjects were dialysis patients (i.e. typically with lower hematocrits) and 124 subjects were normal (i.e. healthy). During the study, no hematocrit dependence was noted based on the subject's health (i.e. whether or not the subject was a dialysis patient had no effect on the CRIT-SCAN II's accuracy).

d. Pigmentation: Although four different ethnic groups were included in the study (Caucasian, African American, Hispanic and Asian), skin pigmentation was used to distinguish the subjects being tested. Each subject was given a pigmentation level between 1 and 3. Level 1 indicated light or fair skin and level 3 indicted dark skin. *NOTE: the pigmentation level given was based on the pigmentation of the subjects "fatty pad" under the finger tip.* Of the 198 subjects, 163 were considered level 1, 26 were considered level 2 and 9 were considered level 3. During the study, no hematocrit dependence was noted based on pigmentation.

e. Hematocrit range: The highest hematocrit measured by the CRIT SCAN II was 54.1 and the lowest hematocrit measured was a 22.7. During the study, no hematocrit dependence was noted based on hematocrit level (i.e. the CRIT-SCAN II was accurate at low and high hematocrits.

f. Finger Size: The circumference of every finger was measured prior to placing the finger into the CRIT-SCAN II Monitor. The smallest circumference measurement taken was 1.6 inches and the largest measurement taken was 2.4 inches. During the study, no hematocrit dependence was noted based on finger size.

g. User Dependencies: It was noted that the CRIT-SCAN II was sensitive to patient movement. Therefore, patients were asked to remain still during the 1 to 2 minute data acquisition phase.

After all 198 data points were gathered, a regression analysis was performed to compare the CRIT-SCAN II data points to the cell counter data points. A comparison of the data resulted in a correlation coefficient of .972 with a standard deviation of 1.44.

9. Conclusions

In conclusion, based on comparison with the industry standard Coulter Counter, the subject CRIT-SCAN II has been found to be safe, accurate and effective in its intended use as a non-invasive, transcutaneous hematocrit monitor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 1999

Mr. Matthew L. Haynie
In-Line Diagnostics Corporation
P.O. Box 685
117 West 200 South
Farmington, UT 84025-0685

Re: K983551
Crit-Scan II Monitor
Regulatory Class: II (two)
Product Code: 81 GKF
Dated: March 1, 1999
Received: March 2, 1999

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) 594-4648. 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,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K983551

Device Name: CRIT-SCAN II MONITOR

Indications for Use:

Section 3 – Intended Use

The intended use of the CRIT-SCAN II Monitor is as a hematocrit-measuring device.

NOTE: The CRIT-SCAN II is not for pediatric use.

(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)

Arthur A. Carlson

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number_____