17 February 2003

APR 17 2003

510(k) Summary

8100 Vital Signs Monitor
w/ Arrhythmia Detection and ST Analysis

Contact: Alex Kaplan
Director of QA & RA
Criticare Systems, Inc.
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262-798-8282 Voice
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Trade Name: 8100 Vital Signs Monitor w/Arrhythmia and ST

Common Name: Vital Signs Monitor

Classification Name: Monitor, Physiological, Patient (74 MWI)

Substantial Equivalence is claimed to : CSI Model 8100/8500 Vital Signs Monitor (K012059)

Device Description:
The 8100 monitor interprets and displays real time physiological data of the patient including waveforms and numerical data. The 8100 can be custom configured to monitor ECG, Noninvasive BP (NIBP), Invasive BP (IBP), S_pO_2, Temperature, Respiration, CO_2, N_2O, O_2 and Halogenated Anesthetic Agents. Arrhythmia Detection and ST Analysis software from Brentwood Medical has been incorporated into the 8100 system and uses the extant ECG hardware inputs and microprocessor to enable these capabilities. All user interface elements are provided by the existing 8100 monitor. For each patient vital parameter, the 8100 will be capable of providing limit alarms and alerts, printing of strip chart recordings and storing data trends for retrospective review.

Intended Use:
This system is intended to monitor physiological parameters of patients within any healthcare environment. The user, responsible to interpret the monitored data made available, will be a professional health care provider. Physiological data, system alarms and patient data analysis will be available to the care provider from the monitor.

Comparison with predicate device:
Criticare Systems Inc. has developed and distributed physiological monitoring devices worldwide since its inception in 1984. The 8100 Vital Signs Monitoring System w/ Arrhythmia Detection and ST Analysis (8100) has the same functions and specifications as the predicate device, the 8100 / 8500 Vital Signs Monitoring System (8100 / 8500), with the addition of Arrhythmia Detection and ST Analysis software algorithms from Brentwood Medical (Brentwood algorithms). The 8100 / 8500 Vital Signs Monitoring System was approved for distribution under the FDA 510(k) file number K012059 and Brentwood Medical's algorithms were previously listed under FDA 510(k) file number K013717. The 8100 / 8500 predicate system is capable of monitoring a number of physiological parameters including ECG, NIBP, IBP, $ETCO_2$, N_2O, O_2, Halogenated Anesthetic Agents, Respiration, Temperature and SpO_2. The patient data collected by the 8100 monitor is displayed for the user on a flat panel display as on the predicate device. The 8100 monitor utilizes Active TFT LCD color display technology. Membrane key panels and rotary push button navigation provides a user interface equivalent to the predicate device. The packaging design of the 8100 monitor is molded plastic, as was the predicate 8100/8500 Vital Signs Monitor. It incorporates audible and visual alarm functions that are activated when set parameter limits are exceeded. The monitoring system is also capable of communicating patient data to the VitalView 24 central monitor for display and alarms as appropriate.

Determination of Substantial Equivalence:

The 8100 monitor has been confirmed to have equivalent performance to the predicate devices for each patient monitoring modality. Additionally, the 8100 complies with safety and performance standards (detailed below) for each monitoring modality and verification of compliance has been completed. AAMI EC-57 testing was performed by Brentwood Medical in their previous submittal (K013717). To document the performance of the Brentwood algorithms when integrated into the 8100 and verify the timeliness of ECG morphology-related alarms, the 8100 was tested with a representative group of prerecorded ECG waveforms with abnormal beats. The patient monitoring technologies present in the 8100 monitor have been in clinical use for at least six years in the predicate 8100 / 8500 (and it's predicate devices, the Scholar 2200 and POET IQ monitors). CSI's field experience with these modalities in the predicate devices has been satisfactory. This combination of equivalence testing, applicable objective standards compliance and field experience substantiates a high level of confidence in the safety and efficacy of the 8100 monitor.

Therefore, the 8100 monitor is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 17 2003

Criticare Systems, Inc.
c/o Mr. Alex Kaplan
Director of QA & RA
20925 Crossroads Circle
Suite 100
Waukesha, WI 53186-4054

Re: K030613
Trade Name: Vital Signs Monitor
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm
Regulatory Class: Class III (three)
Product Code: MHX
Dated: April 3, 2003
Received: April 7, 2003

Dear Mr. Kaplan:

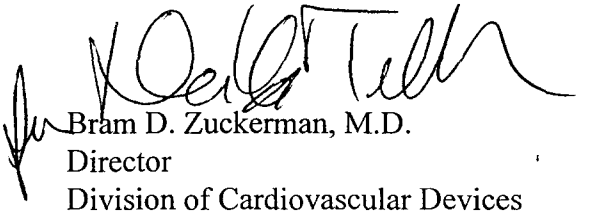
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 such 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 Section 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 (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K030613

510(k) NUMBER (IF KNOWN) : K030613

DEVICE NAME: Vital Signs Monitor

Indications for Use

This system is intended to monitor physiological parameters of patients within any healthcare environment. The user, responsible to interpret the monitored data made available, will be a professional health care provider. Physiological data, system alarms and patient data analysis will be available to the care provider from the monitor.

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

Prescription Use X
(Per 21 CFR 801.109)

OR

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

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K030613