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K012059

16 April 2001

510K Summary

Model 8100 / 8500 Vital Signs Monitor

Contact: Alex Kaplan
Director of QA & RA
Criticare Systems, Inc.
20925 Crossroads Circle
Waukesha, WI 53186 USA
262-798-8282 Voice
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Trade Name: 8100 / 8500 Vital Signs Monitor

Common Name: Vital Signs Monitor

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

Substantial Equivalence is claimed to : CSI Model 2200 Scholar Vital Signs Monitor (K944860) and CSI POET IQ 5-Agent Monitor (K942737)

Device Description:
The 8100 / 8500 monitor measures and displays real time physiological data of the patient, including waveforms and numerical data. The 8100 / 8500 can be configured to monitor one or more of the following parameters: ECG, Noninvasive BP (NIBP), Invasive BP (IBP), SpO2, Temperature, Respiration, CO2, N2O, O2 and Halogenated Anesthetic Agents. For all these vital parameters, the 8100 / 8500 will be capable of limit alarms and alerts, printing of strip chart recordings and storing 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 / 8500 monitor utilizes existing core

technologies from the predicate Scholar 2200 and POET IQ monitors for patient monitoring of ECG, NIBP, IBP, Resp, SpO2, Temp, CO2, N2O, O2 and Halogenated Anesthetic Agents. The patient data collected by the 8100 / 8500 monitor is displayed for the user on a flat panel display as on the predicate devices. The 8100 / 8500 monitor utilizes Passive LCD or Active TFT LCD color display technologies. Membrane key panels and rotary push button navigation provides a user interface equivalent to the predicate devices. The packaging design of the 8100 /8500 monitor is molded plastic and allows for it to be either a stationary monitor or to be used during patient translocation within the healthcare facility, as did the predicate Scholar 2200.

Determination of Substantial Equivalence:

The 8100 / 8500 monitor performance for each monitoring modality has been confirmed to be equivalent to the predicate devices. Additionally, the 8100 / 8500 complies with applicable safety and performance standards (detailed below) for each monitoring modality and verification of compliance has been completed. The patient monitoring technologies present in the 8100 monitor have been in clinical use for at least six years in the 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 / 8500 monitor.

Therefore, the 8100 / 8500 monitor is substantially equivalent to the predicate devices.

Compliance to standards and regulations:
The 8100 / 8500 Vital Signs Monitor complies with the following national and international standards:

Safety
EN 60601-1 Medical Electrical Safety
IEC 601-1-2 EMC Compliance
ISO 10993-5,10-11 Biocompatibility

Performance
EN 60601-2-30 NIBP Safety
EN1060-1 NIBP Performance
EN 1060-3 NIBP Performance {including EN 475 Alarm Performance}
AAMI SP-10 NIBP Performance
IEC 60601-2-27 ECG Safety
AAMI EC-13 Basic ECG Performance
EN 865 Oximetry Performance (Equivalent to ASTM F 1415)
EN 864 Capnometry Performance (Equivalent to ASTM F 1456)
EN 60601-2-34 Invasive Blood Pressure Safety
EN ISO 11196 Anesthetic Gas Monitor Performance (Equivalent to ASTM F 1452)
EN 12598 Oxygen Analyzer Performance (Equivalent to ASTM F 1462)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 2001

Mr. Alex Kaplan
Criticare Systems, Inc.
20925 Crossroads Circle
Waukesha, WI 53186

Re: K012059
Trade Name: 8100/8500 Vital Signs Monitor
Regulatory Number: 21 CFR 870.2300
Regulatory Class: II (two)
Product Code: 74 MWI
Dated: June 29, 2001
Received: July 2, 2001

Dear Mr. Kaplan:

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) 594-4646. 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" (21CFR 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,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN) : K012059

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 ✓ OR Over – the - Counter – Use____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012059