OCT 27 2003

K033283

## 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR § 807.92.

1. The submitter of this premarket notification is:

   Samuel W. Coons III
   CEO
   ICU DataSystems, Inc.
   2153 SE Hawthorne Rd. Suite 220
   Gainesville, FL 32641

   This summary was prepared on August 19, 2003.

2. The name of this device is Centra View™ Device Link System. The common name is Device Link. Current Classification is (74) Cardiovascular, Procode MWI, classification names for an example of the externally connected devices are as follows:

| Regulation Number | Classification Name | Panel | Procode |
|---|---|---|---|
| 870.1110 | Computer, blood pressure | Cardiovascular | 74 DSK |
| 870.1130 | System blood pressure | Cardiovascular | 74 DSJ |
| 870.2300 | Monitor, cardiac | Cardiovascular | 74 DRT |
| 868.5895 | Continuous ventilator | Anesthesiology | 73 CBK |
| 870.2700 | Oximeter | Cardiovascular | 74 QGL |
| 868.1400 | Carbon Dioxide Gas Analyzer | Anesthesiology | 73 CCK |
| 868.2375 | Breathing Frequency Monitor | Anesthesiology | 73 BZQ |
| 880.5725 | IV Infusion Pump | Cardiovascular | 80 DWK |

3. The CentraView ™ Device Link System receives digital data produced by external devices through device specific cables, and displays and stores this information for review by health care professionals.
4. When connected to a bedside device, the CentraView™ Device Link System is intended for electronic data collection and clinical information management. CentraView ™ Device Link System is neither patient connected, nor does it remotely control the attached source device.
5. The CentraView uses the same technology as the predicate device.
6. The CentraView has been tested and complies with UL and IEEE Safety Standards.
7. Additional testing and validation studies were performed.
   a. Device Drive Unit Test
   b. Integration Test Analysis

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 27 2003

ICU DataSystems, Inc.
c/o Ms. Chantel Carson
Engineering Group Leader
Underwriters Laboratories, Inc.
333 Pfingsten Road
Northbrook, IL 60062-2096

Re: K033283
Trade Name: CentraView™
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II (two)
Product Code: MWI
Dated: October 10, 2003
Received: October 14, 2003

Dear Ms. Carson:

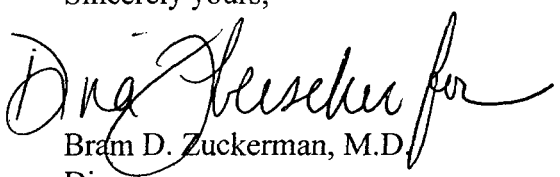
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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

INDICATIONS FOR USE

510(k) Number

Device Name: CentraView™

Indications for Use:

The CentraView patient monitor is intended for monitoring, and recording of multiple physiological parameters. The device is indicated for use in health care facilities by health care professionals whenever there is a need for monitoring of physiological parameters of adult, neonatal, and pediatric patients. CentraView is indicated for use in data collection and clinical information management through cable connections with independent bedside devices. CentraView is not intended for monitoring purposes, nor is it intended to control any of the independent bedside devices it is connected to.

The CentraView System:

- Is intended for use on neonatal, pediatric and adult patients.
- Is intended for use in critical care environments by trained healthcare providers.
- Does not require direct patient contact.
- Is a prescription device which restricts its sale and/or use except by the order of a physician.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033283

Prescription Use X
21 CFR 801.109

OR

Over the counter use___