K062977

K062977 Non-Confidential Summary of Safety and Effectiveness

21-Feb-07

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FEB 2 8 2007

Official Contact: Dalia Givony – Clinical Research, Regulatory and QA Director

Proprietary or Trade Name: CritiView

Model: CRV3

Common/Usual Name: Cardiovascular blood flowmeter
Fluorometer for clinical use

Classification Name: Cardiovascular blood Flowmeter (DPW)
Fluorometer for clinical use (KHO)
Catheter, retention type, balloon accessory (EZL)

Device: CritiView Model CRV3

Predicate Devices: CritiView, CritiSense Ltd, K051145
Mallinckrodt – Foley with temperature – K923538

General Device Description:

The CritiView device carries out certain in-vivo, spectroscopic measurements and displays them as a trend. The parameters measured are blood flow change, blood volume change, and NADH concentration change. It is a multi-parametric monitoring device intended for the measurement of tissue metabolic state. The CritiView device consists of NADH Fluorometer and Doppler Flowmeter. The CritiView (CRV3) device is a modification of the predicate, CritiView, K051145. Measurements are made with the use of optical probes, i.e. pencil type for direct tissue contact and Foley catheter for measurement on the urethral wall tissue.

Indications for Use:

The CritiView Device is indicated for in-vivo monitoring of changes in NADH redox state and microvascular perfusion in tissue. Changes in the measured parameters--blood flow change, blood volume change, and NADH concentration change-- provide information on tissue metabolic activity.

Tissues which may be monitored are: brain, liver, kidney, intestine, testis, skin, and urethra. Note that heart may not be used as the heart beating motion may not provide a reliable probe contact surface.

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Duration of Use:

The CritiView has two probes--a pencil style probe and a Foley catheter probe-- which are in contact with the tissue to be measured / monitored. The optical portion of the probe (device) may be used continuously for up to eight (8) hours per twenty-four (24) hour period.

The Foley can be left in place up to five (5) days.

Patient Population:

Pencil Style Probe: Neonate/infant, pediatric, and adult
Foley Catheter Probe: Hospitalized adults who are clinically indicated for a Foley catheter use.

Environment of use:

Hospital – OR, ICU, Emergency Departments, High Dependency Units Institutions

Contraindications:

The CritiView should not be used on people that are hypersensitive to UV radiation. The device should not be used on patients taking photosensitizing drugs.

When monitoring the urethral wall tissue the device should not be used on patients with urinary tract or bladder infection or in any case when the patient clinical condition prevents the use of a Foley catheter.

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Attribute	CritiView (CRV3)
Indications for use	In-vivo monitoring of changes in NADH redox state and microvascular perfusion in tissue. Changes in the measured parameters--blood flow change, blood volume change, and NADH concentration change-- provide information on tissue metabolic activity.
Environments of use	Hospital – OR, ICU, Emergency Departments, High Dependency Units Institutions
Patient Population	Pencil type probe - Hospitalized patients – Neonate/infant, pediatrics, adults. Foley catheter probe-Hospitalized adults who are clinically indicated for Foley catheter use.
Contraindications	The CritiView should not be used on people that are hypersensitive to UV radiation. The device should not be used on patients taking photosensitizing drugs. When monitoring the urethral wall tissue the device should not also be used on patients with urinary tract or bladder infection or in any case when the patient clinical condition prevents the use of a Foley catheter.
Laser Class	Class 1 Laser Device
Measurement Technique	Absorption, reflection and fluorescence spectrometry
Light source Wavelengths	UV LED – 375 nm Blue LED – 470 nm Green LED – 530 nm NIR Laser Diode – 785 nm
Means for light transmission	In-vivo, fiber optic probe
Measured parameters	1. Blood Flow [%] Doppler Shift 2. Blood Volume [%] of change 3. NADH concentration [%] of change
Power Requirements	110 to 240V ±10
Method of measurement / probe	Direct tissue contact / Pencil type probe; Foley Catheter probe
Duration of use	Optical portion of the probe: Eight (8) hours per twenty-four (24) hours period. Foley catheter: Can be left in placed up to 5 days.
Foley catheter sizes offered	16 and 18 French, for adults only

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Differences Between Other Legally Marketed Predicate Devices:

The new model (CRV3) has a new accessory, a Foley catheter probe intended for the measurement of the urethral tissue. Additionally, battery power operation is possible for the CRV3.

There are no significant differences between the CritiView (CRV3) and the predicate – CritiView, K051145 and between the CritiView Foley catheter probe accessory and the predicate Foley catheter, Mallinckrodt – Foley with temperature – K923538.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 28 2007

CritiSense Ltd.
c/o Mr. Paul E. Dryden
President
3460 Ponte Creek Court #102
Bonita Spring, FL 34134-2015

Re: K062977
Trade/Device Name: CritiView Model CRV3
Regulation Number: 21 CFR 870.2100
Regulation Name: Cardiovascular Blood Flowmeter
Regulatory Class: Class II (two)
Product Code: DPW, EZL and KHO
Dated: February 1, 2007
Received: February 2, 2007

Dear Mr. Dryden:

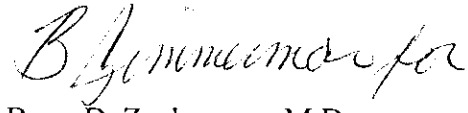
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (240) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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 Statement

510(k) Number: K062977

Device Name: CritiView (CRV3)

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Environment of use:
Hospital – OR, ICU, Emergency Departments, High Dependency Units Institutions

Prescription Use XX
(Per CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

B Hammond

Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K062977

Indications for Use Statement

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