DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 23, 2014

The Surgeon General, Department of the Army
Dr. Kenneth A. Bertram
Principal Assistant for Acquisition
1430 Veterans Drive
Fort Detrick, Maryland 21702

Re: K140387
Trade/Device Name: Burn Resuscitation Decision Support System – Clinical (BRDSS-C), v. 1.0
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive pulmonary-function value calculator
Regulatory Class: Class II
Product Code: PDT
Dated: November 24, 2014
Received: November 25, 2014

Dear Dr. Bertram:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140387

Device Name
Burn Resuscitation Decision Support System – Clinical (BRDSS-C), v. 1.0

Indications for Use *(Describe)*
The BRDSS-C is indicated for use in the care of adult patients and adolescent patients 17 years of age or older who weigh 40kg (88lbs) or more with 20% or more Total Body Surface Area (TBSA) burned, as a fluid resuscitation calculator for fluid recommendations. The BRDSS-C is intended to be initiated within 24 hours of the burn incident and completed by 72 hours post burn. The BRDSS-C is not indicated for use in patients who are less than 17 years of age.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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BURN RESUSCITATION DECISION SUPPORT SYSTEM - CLINICAL (BRDSS-C), v. 1.0

Submitted by:	Office of Surgeon General, Department of Army
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Manufacturer:	Jose Salinas, PhD Burn Intensive Care Unit, U.S. Army Burn Center U.S. Army Institute of Surgical Research 3698 Chambers Pass Joint Base San Antonio, Fort Sam Houston, TX 78234-6315 Telephone: 210-916-3301 Fax: 210-271-0830
Date Prepared:	17 December 2014

Trade Name:	Burn Resuscitation Decision Support System - Clinical (BRDSS-C), v. 1.0
Common Name:	Software-based fluid volume calculator
Regulation Number:	21 CFR 868.1890
Classification Name:	Predictive pulmonary-function value calculator.
Regulatory Class	Class II
Product Code:	PDT
Predicate Device:	K121659 Burn Resuscitation Decision Support System (BRDSS)
Device Description:	The Burn Resuscitation Decision Support System – Clinical (BRDSS-C) is a burn decision support software application for assisting healthcare professionals in managing fluid resuscitation of burn patients during the initial 24 - 72 hours post burn. The system provides hourly (or half-hour) fluid calculations and recommendations for patients with 20% or greater Total Body Surface Area (TBSA) burn injuries, in addition to providing users with a graphical user interface to display volume status, Intake and Output (I/O) volumes, and other relevant fluid balance information.

Indications for Use

The BRDSS-C is indicated for use in the care of adult patients and adolescent patients 17 years of age or older who weigh 40kg (88lbs) or more with 20% or more Total Body Surface Area (TBSA) burned, as a fluid resuscitation calculator for fluid recommendations. The BRDSS-C is intended to be initiated within 24 hours of the burn incident and completed by 72 hours post burn. The BRDSS-C is not indicated for use in patients who are less than 17 years of age.

Predicate Device Comparison

The predicate device, Burn Resuscitation Decision Support System (BRDSS), is now known as the BRDSS (Burn Navigator) by Arcos™ (Houston, TX). Therefore, the predicate device will be referred to as BRDSS (Burn Navigator) throughout this 510(k). Table 1 presents a summary comparison of the technological characteristics of predicate device and the BRDSS-C. Table 2 summarizes the differences in physical/technological characteristics and intended use statements between the two devices.

Table 1 Comparison of Technological Characteristics

	Predicate Device K121659 BRDSS (Burn Navigator)	**Burn Resuscitation Decision Support System – Clinical, v. 1.0 (BRDSS-C)**
Device Description	The BRDSS (Burn Navigator) is a tablet computer containing the burn decision support algorithm for use by healthcare professionals in managing fluid resuscitation of burn patients during the initial 24 - 72 hours post burn. BRDSS (Burn Navigator) is an hourly fluid calculator for patients with 20% or more TBSA burn injuries	The Burn Resuscitation Decision Support System – Clinical (BRDSS-C) is a burn decision support algorithm available on a server for use on a desktop computer by healthcare professionals in managing fluid resuscitation of burn patients during the initial 24 - 72 hours post burn. The BRDSS-C algorithm is the same algorithm contained in the BRDSS (Navigator). BRDSS-C is an hourly (or half-hour) fluid calculator for patients with 20% or more TBSA burn injuries.
Displayed Information	BRDSS (Burn Navigator) provides users with a graphical user interface to display volume status, Intake and Output (I/O) volumes and other relevant fluid balance information.	BRDSS-C provides users with a graphical user interface to display volume status, Intake and Output (I/O) volumes and other relevant fluid balance information. The system also displays vital sign, clinical and laboratory data from Essentris®, a connected electronic medical record system.
Software-Based	Yes	Yes
Information Storage	BRDSS (Burn Navigator) stores information on multiple burn patients but allows resuscitation of only one patient at a time.	BRDSS-C stores information on multiple burn patients but allows resuscitation of only one patient at a time.
Indications for Use	BRDSS (Burn Navigator) is indicated for use in the care of adult patients weighing 40 kg or more with 20% or more TBSA burned, as a fluid resuscitation calculator for hourly fluid recommendations; it is not intended for pediatric use. The BRDSS (Burn Navigator) is intended to be initiated within 24 hours of the burn incident and completed by 72 hours post burn.	BRDSS-C is indicated for use in the care of adult patients and adolescent patients 17 years of age or older who weigh 44kg (88lbs) or more with 20% or more TBSA burned, as a fluid resuscitation calculator for hourly (or half-hour) fluid recommendations. The BRDSS-C is intended to be initiated within 24 hours of the burn incident and completed by 72 hours post burn. The BRDSS-C is not indicated for use in patients who are less than 17 years of age.

	Predicate Device K121659 BRDSS (Burn Navigator)	**Burn Resuscitation Decision Support System – Clinical, v 1.0 (BRDSS-C)**
Intended User	Healthcare professional	Healthcare professional
Intended Use Environment	Hospital critical care facility or transport vehicle	Hospital critical care facility
Human Factors	Physician or nurse enters patient weight, % of body surface area burned and time of burn. Warnings are presented when the primary fluid rate recommendation is ± 25% (and ± 200mL/hr.) from the current primary fluid rate. In addition, graphs are included to show the cumulative volume of fluids received and urine output.	Nurse enters patient weight, % of body surface area burned and time of burn. Warnings are presented when the primary fluid rate recommendation is ± 25% from the current primary fluid rate. In addition, graphs are included to show the cumulative volume of fluids received and urine output. Connection to Essentris® also provides vital signs and laboratory and clinical data for display.
Rate Calculation	Yes	Yes

Table 2 Summary of Device Differences

Predicate Device K121659 BRDSS (Burn Navigator)	**Burn Resuscitation Decision Support System – Clinical, v. 1.0 (BRDSS-C)**	**Impact on Safety and Effectiveness**
Table computer	Desktop computer	Safety and effectiveness are not bound by the physical device. System validation proves system effectiveness.
Hardware-specific medical device	Software medical device	Safety and effectiveness are not bound by the physical device. System validation proves system effectiveness.
Touch screen	Input devices are keyboard and mouse	Input devices have no change to system functionality dealing with patient safety or system effectiveness.
Device is an all-inclusive unit	Application requires installation onto an existing computer network	System effectiveness is not determined by the physical device.
Records data to the tablet hard drive	Data are saved in Oracle database	Oracle is a proven product with tools for database management and proven encryption for data security.

Predicate Device K121659 BRDSS (Burn Navigator)	Burn Resuscitation Decision Support System – Clinical, v. 1.0 (BRDSS-C)	Impact on Safety and Effectiveness
Intended for use by medical staff, but not necessarily staff with burn care experience.	Intended for use by healthcare professionals with burn care experience.	Use by experienced burn unit healthcare providers adds a layer of safety to the device. System validation proves system effectiveness.
Not intended for use in pediatric patients.	Intended for use in patients 17 years of age or older. Patients who are 21 years of age or younger at the time of diagnosis or care are pediatric patients (21CFR814.3).	Use of either device is restricted to patients who weigh 44kg or more. Use either device in older adolescent patients will not affect the safety and effectiveness of the device.
N/A	Requires User Manager for user access (User Manager must be installed and the BRDSS-C user added and configured correctly before the user can access BRDSS-C.) The DOD Common Access Card (CAC) is used for system (desktop) and BRDSS-C application access. User Manager is configured to use CAC credentials.	Additional security for user access makes the system more secure. No change to system functionality dealing with patient safety or system effectiveness.

Non-clinical Performance Data

The BRDSS-C adheres to software requirements such as data intake validation, user warnings, alerts and messages, user interface requirements, functional requirements and error handling requirements. A human factors study was conducted and demonstrated that the software is compliant with human factors usability requirements. The BRDSS-C has passed software verification and validation as well as clinical user validation based on the FDA's Quality System Regulation requirements under 21 CFR Part 820.

Substantial Equivalence

BRDSS-C and the predicate device, BRDSS (Burn Navigator), are both software-based fluid calculators intended to be used by healthcare professionals to calculate resuscitation fluid volumes for burn patients during the initial 24 - 72 hours post burn. Both devices provide rate calculations based on the same burn decision support algorithm using patient physical (e.g. TBSA and body weight) and clinical data (e.g. intravenous fluid infused). The BRDSS (Burn Navigator) is operated on a tablet computer and the BRDSS-C is operated from a standard desktop computer. Physical differences between the two devices do not affect the burn decision support algorithm. Both devices are not intended for use in patients who weigh less than 44kg (88lbs).

Based upon the above information, the BRDSS-C is substantially equivalent to the predicate device in terms of intended use and technical features; any differences do not raise new safety and effectiveness questions.