DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 15, 2014

Medical Decision Network, LLC
C/O Jane Keathley, MS
Regulatory Project Manager
2220 Ivy Road, Suite 403
Charlottesville, Virginia 22903

Re: K141321
Trade/Device Name: GlucoStabilizer® Insulin Dosing Calculator
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive pulmonary-function value calculator
Regulatory Class: II
Product Code: NDC
Dated: August 5, 2014
Received: August 6, 2014

Dear Ms. Keathley:

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,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental 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)*
K141321

Device Name
GlucoStabilizer Insulin Dosing Calculator

Indications for Use *(Describe)*
The GlucoStabilizer Insulin Dosing Calculator 3.0 is designed for use by order of a physician for hospitalized patients. It is intended to evaluate the current as well as cumulative patient blood glucose values, and based on those measurements, calculate and recommend a dose of insulin or dextrose to drive the blood glucose level either up or down towards a predetermined target range.

Once that target blood glucose range has been reached, the system's function is to recommend dosing of insulin or dextrose for the purpose of maintaining the patient's blood glucose level in that target range. The system is programmed to provide intravenous dosing calculations of insulin and dextrose for both adult and pediatric (ages 2 to <18 years) patients with no known insulin allergies.

The GlucoStabilizer Insulin Dosing Calculator's programmed logic is not a substitute for, but rather an assist to clinical reasoning. The measurements and calculations generated by the GlucoStabilizer Insulin Dosing Calculator are intended to be used by qualified and trained medical personnel in evaluating patient conditions in conjunction with clinical history, symptoms, and other diagnostic measurements, as well as the medical professional's clinical judgment. No medical decisions should be based solely on the recommended guidance provided by this software program.

Contraindications:
The device is not intended for use with patients with known insulin allergies or patients under the age of 2 years.

Warnings and Precautions:
The GlucoStabilizer Insulin Dosing Calculator's programmed logic is not a substitute for, but rather an assist to clinical reasoning. The measurements and calculations generated by the GlucoStabilizer Insulin Dosing Calculator are intended to be used by qualified and trained medical personnel in evaluating patient conditions in conjunction with clinical history, symptoms, and other diagnostic measurements, as well as the medical professional's clinical judgment. No medical decisions should be based solely on the recommended guidance provided by this software program.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5. 510(k) Summary K141321

Date:	Sep-10-2014
Owner/Submitter:	Greg Menke Medical Decision Network, LLC 2220 Ivy Road, Suite 403 Charlottesville, VA 22903 Phone: 866-791-6108 Fax: 434-202-7282
Contact:	Jane Keathley, MS Regulatory Project Manager Medical Decision Network, LLC 2220 Ivy Road, Suite 403 Charlottesville, VA 22903 Phone: (434) 409-3535 Email: jane.keathley@mdnllc.net
Type of 510(k) Submission:	Traditional 510(k)
Trade Name:	GlucoStabilizer® Insulin Dosing Calculator (*Formerly Clarian Glucose Stabilizer Insulin Dosing Calculator)*
Common Name:	GlucoStabilizer *(Formerly MDN-CGS™ Insulin Dosing Calculator)*
Establishment Registration Number:	3010817588
Review Panel/Medical Specialty:	Anesthesiology
Product Code:	NDC
Classification Name:	Drug Dose Calculator
Classification Number:	21 CFR 868.1890
Class:	2
Predicate Device:	MDN-CGS™ Insulin Dosing Calculator (K071713) Glytec LLC, Glucommander™ System (K113853)

Description of Device:	The GlucoStabilizer Insulin Dosing Calculator 3.0 is a Web-based software solution that automates calculations used by healthcare professionals to determine the appropriate intravenous insulin drip rate necessary to manage blood glucose levels across a variety of patient populations. GlucoStabilizer also provides alerts for subsequent blood glucose testing and monitoring. The GlucoStabilizer software release described in this 510(k) submission contains a modification that allows its use for pediatric patients. The pediatric protocol considers patient weight in insulin calculations for patients under the age of 18 years and provides a 3-digit multiplier for more granular calculation results. In addition, this release of GlucoStabilizer provides an optional 'multi-view' screen that allows healthcare personnel to more easily manage multiple, on-going patient treatment programs. Other features and technological characteristics of GlucoStabilizer are unchanged.
Intended Use:	The GlucoStabilizer Insulin Dosing Calculator 3.0 is designed for use by order of a physician for hospitalized patients. It is intended to evaluate the current as well as cumulative patient blood glucose values, and based on those measurements, calculate and recommend a dose of insulin or dextrose to drive the blood glucose level either up or down towards a predetermined target range. Once that target blood glucose range has been reached, the system's function is to recommend dosing of insulin or dextrose for the purpose of maintaining the patient's blood glucose level in that target range. The system is programmed to provide intravenous dosing calculations of insulin and dextrose for both adult and pediatric (ages 2-<18) patients with no known insulin allergies. The GlucoStabilizer Insulin Dosing Calculator's programmed logic is not a substitute for, but rather an assist to clinical reasoning. The measurements and calculations generated by the GlucoStabilizer Insulin Dosing Calculator are intended to be used by qualified and trained medical personnel in evaluating patient

	conditions in conjunction with clinical history, symptoms, and other diagnostic measurements, as well as the medical professional's clinical judgment. No medical decisions should be based solely on the recommended guidance provided by this software program.
Comparison with Predicate Device:	The submission device and the predicate devices have the same general intended use and similar indications, technological characteristics, and principles of operation. Each of the devices is intended to be used by trained clinicians. This release of GlucoStabilizer includes support for use with pediatric patients, similar to Glytec LLC, Glucommander™ System.
Conclusion:	GlucoStabilizer Insulin Dosing Calculator 3.0 has the same technological characteristics and principles of operation as the MDN-CGS™ Insulin Dosing Calculator and Glytec LLC, Glucommander™ System. GlucoStabilizer 3.0 has the same intended use and similar indications as the Glucommander System. The minor technological differences between the GlucoStabilizer 3.0 and its predicates do not present any new issues of safety or effectiveness. Thus, the GlucoStabilizer Insulin Dosing Calculator 3.0 is substantially equivalent to the MDN-CGS™ Insulin Dosing Calculator (K0717130) and the Glytec LLC, Glucommander™ System (K113853).