5. 510(k) Summary

Date:	June 21, 2007 OCT 1 2 2007
Submitter:	Medical Decisions Network, Inc. 2000 Holiday Drive, Suite 200 Charlottesville, VA 22901
Contact:	Medical Decisions Network, Inc. c/o Mr. Jonathan S. Kahan Hogan & Hartson LLP 555 Thirteenth Street, NW Washington, DC 20004 Phone: (202) 637-5600 Fax: (202) 637-5910 Email: jskahan@hhlaw.com
Trade Name:	Clarian Glucose Stabilizer Insulin Dosing Calculator
Common Name:	MDN-CGS™ Insulin Dosing Calculator
Classification Name: Classification Number: Product Code:	Drug Dose Calculator Class II (per 21 CFR 868.1890) NDC
Predicate Device:	EndoTool™ Drug Dose Calculator (K053137) Glucommander Plus™ (K061110)
Description of Device:	The MDN-CGS™ Insulin Dosing Calculator 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. The MDN-CGS™ Insulin Dosing Calculator also provides alerts for subsequent blood glucose testing and monitoring.
Intended Use:	The MDN-CGS™ Insulin Dosing Calculator is intended to evaluate the

current patient blood glucose values. Based on the measurements, the software will calculate either a dose of glucose or insulin to drive the blood glucose level up or down toward a predetermined target range. Once that target blood glucose range has been reached, the software program calculates dosing of insulin or glucose 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 glucose or insulin. The device is intended for use with patients with no known insulin allergies and for patients over the age of 18.

The MDN-CGS™ Insulin Dosing Calculator's programmed logic is a tool and not a substitute for, but rather an assist to, clinical reasoning. The measurements and calculations generated by the MDN-CGS™ Insulin Dosing Calculator are intended to be used by qualified and trained medical personnel directed by physician order. No medical decisions are to be made solely on the guidance provided by this software program, but are to include consideration of clinical history, symptoms, other diagnostic measurements, and the professional's clinical judgment.

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. The only technological difference between the MDN-CGS™ Insulin Dosing Calculator and its predicates is that the MDN-CGS™

	Insulin Dosing Calculator is a stand-alone software device, while the predicate software programs are accessories to automated insulin pumps.
Conclusion:	The MDN-CGS™ Insulin Dosing Calculator and the Endotool and Glucommander Plus have the same intended use and similar indications, technological characteristics and principles of operation. The minor technological differences between the MDN-CGS™ and its predicates do not present any new issues of safety or effectiveness. Thus, the MDN-CGS™ Insulin Dosing Calculator is substantially equivalent to the EndoTool™ Drug Dose Calculator (K053137) and the Glucommander Plus™ (K061110).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 12 2007

Medical Decisions Network, Incorporated
C/O Mr. Jonathan S. Kahan
Partner
Hogan & Hartson LLP
555 Thirteenth Street, North West
Washington, DC 20004

Re: K071713
Trade/Device Name: Clarian Glucose Stabilizer Insulin Dosing Calculator
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive Pulmonary-Function Value Calculator
Regulatory Class: II
Product Code: NDC
Dated: September 21, 2007
Received: September 21, 2007

Dear Mr. Kahan:

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): K071713

Device Name: Clarian Glucose Stabilizer Insulin Dosing Calculator

Indications for Use:

The MDN-CGS™ Insulin Dosing Calculator is intended to evaluate the current patient blood glucose values. Based on the measurements, the software will calculate either a dose of glucose or insulin to drive the blood glucose level up or down toward a predetermined target range. Once that target blood glucose range has been reached, the software program calculates dosing of insulin or glucose 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 glucose or insulin. The device is intended for use with patients with no known insulin allergies and for patients over the age of 18.

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)
510(k) Number: K071713

for ADW

September 20, 2007