K081388

510(k) Summary
for the Pronia Medical Systems, LLC
GlucoCare IGC System

AUG 21 2008

1. SUBMITTER/510(K) HOLDER

Pronia Medical Systems, LLC
7527 Beechspring Farm Boulevard
Louisville, KY 40241

Contact Person: Brian J. Besterman, M.D.
Telephone: (914) 261-6622

Date Prepared: May 16, 2008

2. DEVICE NAME

Proprietary Name:	GlucoCare IGC System
Common/Usual Name:	Dose Calculation Software
Classification Name:	Drug Dose Calculator
Classification:	Class II (per 21 CFR 868.1890)
Product Code:	NDC

3. PREDICATE DEVICES

- EndoTool™ Glucose Management System, K053137
- MDN-CGS™ Insulin Dosing Calculator, K071713

4. DEVICE DESCRIPTION

The GlucoCare IGC System is a software program that implements an insulin infusion protocol intended for the treatment of hyperglycemic adult patients in a healthcare facility. The software directs insulin infusion rates based on the patient's blood glucose level history and target blood glucose level.

Audible and visual alerts remind the medical staff when it is time to take blood glucose readings or change insulin drip rates. The system provides a complete time/date/username-stamped history of all patient activity in text and graphical formats, both on-screen and in a printable form.

The GlucoCare IGC System software resides on the GlucoCare application server. Local client computers interact with the GlucoCare IGC System software using HTTPS.

5. INTENDED USE

The GlucoCare IGC System is a software program indicated for the management of patient blood glucose levels a healthcare facility setting. The GlucoCare IGC System software, using an algorithm that is based on an established clinical protocol, calculates the dosage of insulin required to maintain the blood glucose level within a target range set by the protocol. No medical decisions are made by the GlucoCare IGC System software. The information provided by the software is intended to be used as a tool by qualified, trained medical personnel. The GlucoCare IGC System software is intended for use in adults over the age of 18 with no known insulin allergies. The device is not intended for use in patients with diabetic ketoacidosis.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Pronia Medical Systems GlucoCare IGC System and the predicate devices are all software programs that dictate insulin dosing instructions based on the patient's blood glucose levels over time. The proposed and predicate software all issue alerts and provide instructions for the timing and frequency of blood glucose testing and the need to infuse glucose to prevent hypoglycemia.

The proposed and predicate devices have the same general intended use and similar indications, technological characteristics, and principles of operation. Any minor technological differences between the GlucoCare IGC System and its predicates do not present any new issues of safety or effectiveness. Thus, the GlucoCare IGC System is substantially equivalent to the EndoTool™ Glucose Management System (K053137) and the MDN-CGS™ Insulin Dosing Calculator (K071713). A comparison of the intended use and technological characteristics of the proposed and predicate devices is provided in Table 5-1.

7. PERFORMANCE TESTING

Software verification and validation testing activities were conducted to establish the performance, functionality, and reliability characteristics of the GlucoCare IGC System. Testing included unit testing, integration testing, system testing, and functional testing. The results of the testing confirmed that the GlucoCare IGC System performed as intended.

Table 5-1. Comparison Table for Determination of Substantial Equivalence

Category	GlucoCare IGC System	EndoTool™ Glucose Management System, K053137	MDN-CGS™ Insulin Dosing Calculator, K071713
Intended Use	Intended for use by trained medical personnel for the management of patient blood glucose levels in the hospital setting		
Patient Population	Variety of different patient populations	Critically ill patients on continuous feeding	Variety of different patient populations
Principle of Operation	Using blood glucose measurements, software algorithms determine appropriate insulin dosing in accordance with established treatment protocols		
Hardware	Web based network with PC running web browser	Web based network with Windows PC	Standalone Windows PC
Features	Provides alerts for subsequent blood glucose testing and monitoring	Provides alerts for subsequent blood glucose testing and monitoring	Provides alerts for subsequent blood glucose testing and monitoring

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Pronia Medical System, LLC
C/O Cynthia J. M. Nolte, Ph.D., RAC
Senior Regulatory Consultant
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

AUG 21 2008

Re: K081388
Trade/Device Name: Pronia Medical Systems, LLC, GlucoCare Intensive Glycemic Control System
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive Pulmonary-Function Value Calculator
Regulatory Class: II
Product Code: NDC
Dated: August 6, 2008
Received: August 7, 2008

Dear Dr. Nolte:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

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

Indications for Use

510(k) Number: K081388

Device Name: Pronia Medical Systems, LLC GlucoCare IGC System

Indications for Use:

The GlucoCare IGC System is a software program indicated for the management of patient blood glucose levels in the hospital setting. The GlucoCare IGC System software, using an algorithm that is based on an established clinical protocol, calculates the dosage of intravenously administered insulin required to maintain the blood glucose level within a target range set by the protocol. No medical decisions are made by the GlucoCare IGC System software. The information provided by the software is intended to be used as a tool by qualified and trained medical personnel. The GlucoCare IGC System software is intended for use in patients over the age of 18 with no known insulin allergies. The device is not intended for use in patients with diabetic ketoacidosis.

Prescription Use ___X___ AND/OR Over-The-Counter Use____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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