510(k) Summary

In accordance with the requirements of SMDA 1990 and 21 CFR 807.92, this 510(k) Summary is provided:

1. Submitted by:

CollaborativeMed, LLC
14-D Pelham Ridge Dr.
Greenville, SC 29615

Phone: 864-370-3297
Fax: 864-233-7828
Contact: Robert Booth

2. Date Prepared:

December 12, 2005

3. Classification of Device:

Classification Code: NDC
Drug Dose Calculator, Class II
Regulation Number: 868.1890
Device Class: Class II

4. Trade Name of Proposed Device:

Glucommander Plus

5. Predicate Device:

K040676, MiniMed Medtronic Paradigm Insulin Pump
K042873, Animas Model IR1250 Insulin Infusion Pump
K023674, Phillips Drug Calculator
K043600, Medtronic MicroMed 407C
K961486, IVAC MedSystem III, Infusion Pump w/ Drug Editing
K051079, Hopira Gemstar Infusion Pump System

6. Proposed Device Description:

The Glucommander is a simple, automated, computer-based software application that, based on frequent patient glucose measurement inputs, calculates and recommends titration of intravenous and subcutaneous insulin infusion rates and intravenous glucose infusion and oral glucose consumption rates, calculated to medicate a patient's blood glucose level towards a specified target range. The Glucommander also provides alarms and warnings, as well as alerts for subsequent blood glucose testing and monitoring.

7. Statement of Intended Use:

The Glucommander is intended to evaluate the current as well as cumulative patient blood glucose values, and based o the aggregate of those measurements, whether one or many, calculate and recommend a dose of saline, glucose, and insulin 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, glucose, and saline for the purpose of maintaining the patient's blood glucose level in that target range. The system is programmed to provide intravenous dosing of glucose, saline, and insulin; as well as subcutaneous dosing of glucose and insulin. The device is not intended for use with patients with known insulin allergies or patients under the age of 18.

The glucommander's programmed logic is not a substitute for, but rather an assist to clinical reasoning. The measurements and calculations generated by the GBGDS 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 decision should be based solely on the recommended guidance provided by this software program.

8. Comparison of the Technological Features of the Device Predicate Devices:

The technological features of the Glucommander do not differ from the previously cleared predicate devices.

Factor	**Subject Device** Glucommander Plus	**Predicate Device** IVAC MedSystem III Infusion Pump w/ Drug Editing
Dose Titration	Titrates drug dosage	Same
Infusion Rate Calculations	Calculates intravenous infusion Rate of delivery for fluids and medications	Same
User Input	Receives input from user to Calculate dosage	Same
Indications for Use	Indicated for use as an accessory to an infusion pump.	Same

Factor	**Subject Device** Glucommander Plus	**Predicate Device** Hopira Gemstar Infusion Pump System
Intended Use	Intended for use with Intravenous arterial, Subcutaneous, and parenteral Administration of general I.V. fluid, medications, and nutritional fluids	Same
Indications for use	Indicated for use as an accessory To an infusion pump and intended for use include hospital and ambulatory environments.	Same
Operations	Provides Indications of several functions including operations, alarms, program status, and the parameters of fluid flow	Same

Factor	**Subject Device** Glucommander Plus	**Predicate Device** Phillips Drug Calculator

Dose Computation	Software-based application used to compute drug dosing	Same
Operations	Utilizes alarms and alerts to notify user	Same
Algorithms	Uses a mathematical algorithm to give directions for dosing	Same

Factor	**Subject Device** Glucommander Plus	**Predicate Device** Animas Model IR1250 Insulin
Computer-Based	Computer-implemented method Of managing the blood glucose Level of a patient with diabetes	
Interface	Provides and interface which allows a healthcare provider to Input different types of data used to calculate insulin, glucose, and carbohydrate intake recommendations for the patient	Same
Data Storage	Timestamps and stores patient's blood glucose data	Same
Nutritional Bolus	Uses a carbohydrate formula to calculate a nutritional bolus	Same
Data Analysis	Analyzes blood glucose data, meal intake data, and trends Associated with the food intake of a patient, and insulin intake data associated with the insulin intake of the patient	Same
Alarms	Executes programmed reminders and alarms for users to check blood glucose	Same
Corrective calculations	Recommends insulin dosing to compensate for hyperglycemia, based on corrective calculations	Same

Factor	**Subject Device** Glucommander Plus	**Predicate Device #1** MiniMed Medtronic Paradigm Insulin Pump
Dose Titration	Recommends appropriate amount of insulin for subcutaneous delivery	Same
Patient Profile	Insulin delivery profile is based on target blood glucose, carbohydrate insulin ratio, and	Same

	insulin sensitivity	
Dosing Computations	Computes insulin dosing	Same
Data Storage	Tracks time period in which insulin is administered and stores Blood glucose and insulin history data	Same
Warnings	Indicates warning in conditions under which excessive dosing would be calculated	Same
Data Download	Ability to download trend data to A PC for physician analysis	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 7 2006

CollaborativeMed, LLC
C/O Ms. Michelle S. Lee
Responsible Third Party Official
Underwriters Laboratories, Incorporated
2600 NW Lake Road
Camas, Washington 98607-9526

Re: K061110
Trade/Device Name: Glucommander Plus
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive Pulmonary-Function Value Calculator
Regulatory Class: II
Product Code: NDC
Dated: May 23, 2006
Received: May 25, 2006

Dear Ms. Lee:

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) 276-0115. 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,

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

K961114

Indications for Use

510(k) Number (if known):

Device Name: Glucommander Plus

Indications For Use:

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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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

...ion Sign-Off)
...sion of Anesthesiology, General Hospital,
...ction Control, Dental Devices

...(k) Number: K961114