JUN 2 8 2010

K101344

Glytec, LLC G+ System (Glucommander Plus System)
Special 510(k) Premarket Notification

510(k) Summary of Safety and Effectiveness

Proprietary Name:	Glytec LLC, G+ System
Common Name:	G+ System™
Product Code/Classification Panel:	NDC – General and Plastic Surgery
Classification Name:	Drug Dose Calculator Class II per §868.1890

Submitter Information

Submitter's Name and Address:

Glytec, LLC (a wholly owned subsidiary of Glucotec, Inc., formally known as CollaborativeMed, LLC)
665 N. Academy Street
Greenville, SC 29601
FDA Establishment Registration Number: 3005853093

Contact Information:

William Matthews, Managing Partner
BioDevice Solutions, LLC
2607 Woodruff Rd.
Simpsonville, SC 29681
Telephone (760) 574-9476
Fax (864) 297-5270

Performance Standards

No applicable performance standards have been issued under section 514 of the Food, Drug and Cosmetic Act for Automatic Peritoneal Delivery Systems.

Predicate Device

The predicate device for the GlyTec, LLC G+ System is the following:

- CollaborativeMed, LLC Glucommander Plus (G+) System - #K061110 (6/7/2006);

Glytec, LLC G+ System (Glucommander Plus System)
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Device Description

The Glytec, LLC G+ System is a software device intended to evaluate the current as well as cumulative patient blood glucose values, and, based on the aggregate of those measurements, whether one or many, regulate the infusion of I.V. fluids, through an I.V. infusion pump, and direct the blood glucose level towards a predetermined target range. Once that target blood glucose range has been reached, the system's function is to recommend a titration 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 available in a Standard Edition or server based Enterprise Edition.

Indications for Use/Intended Use

The G+ System is intended to evaluate the current as well as cumulative patient blood glucose values, and, based on the aggregate of those measurements, whether one or many, regulate the infusion of I.V. fluids, through and I.V. infusion pump, and drive the blood glucose level towards a predetermined target range. Once that target blood glucose range has been reached, the system's function is to recommend a titration 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 G+ System logic is not a substitute for, but rather an assist to clinical reasoning. The measurements and calculations generated 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.

Statement of Substantial Equivalence

Glytec, LLC believes that, within the meaning of the Medical Device Amendments of 1976, the Glytec, LLC G+ System is substantially equivalent to the following medical device in commercial distribution:

- CollaborativeMed, LLC, Glucommander Plus - #K061110 (6/7/2006)

510(k) Summary of Safety and Effectiveness

Conclusion

Based upon an analysis of the overall performance characteristics for the Glytec, LLC, G+ System, Glytec, Inc. believes that no significant differences exist between this system and the predicate systems quoted therefore, the Glytec, LLC G+ System does not impose any new safety or effectiveness concerns.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 2 8 2010

Glytec, LLC (Formally known as GlucoTec, Incorporated)
C/O Mr. William Matthews
BioDevice Solutions, LLC
2607 Woodruff Road
Simpsonville, South Carolina 29681

Re: K101344
Trade/Device Name: G+™ System
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive Pulmonary - Function Value Calculator
Regulatory Class: II
Product Code: NDC
Dated: June 17, 2010
Received: June 18, 2010

Dear Mr. Matthews:

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.

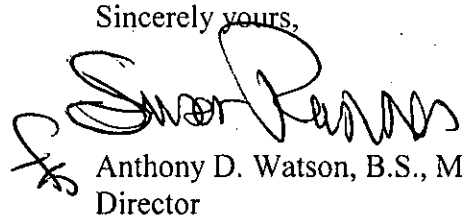
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,



Anthony D. Watson, B.S., M.S., M.B.A.
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 (if known): K011344

Device Name: **G+™ System**

Indications For Use:

The Glucommander is intended to evaluate the current as well as cumulative patient blood glucose values, and, based on 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 he recommended guidance provided by this software program.

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

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

510(k) Number: K011344