K113853

MAY - 8 2012

Glytec, LLC Glucommander System
510(k) Premarket Notification

Section 3
510(k) Summary of Safety and Effectiveness

April 30, 2012

Proprietary Name:	Glytec LLC, Glucommander™ System
Common Name:	G+ System, Enterprise Edition
Product Code/Classification Panel:	NDC – General and Plastic Surgery
Classification Name:	Predictive Pulmonary Function Value Calculator, Class II per §868.1890

Submitter Information

Submitter's Name and Address:

Glytec, LLC (a wholly owned subsidiary of Glucotec, Inc.)
770 Pelham Rd., Ste 210
Greenville, SC 29615
FDA Establishment Registration Number: 3005853093

Contact Information:

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Glytec, LLC
770 Pelham Rd., Ste 210
Greenville, SC 29615
Phone 864-263-4180
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Performance Standards

No applicable performance standards have been issued under section 514 of the Food, Drug and Cosmetic Act for a Predictive Pulmonary Function Value Calculator §868.1890.

Predicate Device

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

Section 3
510(k) Summary of Safety and Effectiveness

April 30, 2012

- GlyTec, LLC G+ System - #K101344 (6/28/2010)

Device Description

The Glytec, LLC Glucommander System is a software device used to evaluate current and cumulative patient blood glucose values, and, based on the aggregate of those measurements, whether one or many, recommend an IV dosage of insulin, glucose or saline to 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 insulin for both pediatric (ages 2 – 17 years) and adult patients.

Indications for Use/Intended Use

The Glucommander System is a glycemic management tool intended to evaluate current and cumulative patient blood glucose values and coupled with patient information including age, weight and height, and, based on the aggregate of these measurement parameters, whether one or many, recommend an IV dosage of insulin, glucose or saline or a subcutaneous basal and bolus insulin dosing recommendation to adjust and maintain the blood glucose level towards a configurable clinician determined target range.

The Glucommander System is indicated for use in adult and pediatric (ages 2 – 17 years) patients.

The Glucommander System logic is not a substitute for, but rather an adjunct 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.

Section 3
510(k) Summary of Safety and Effectiveness

April 30, 2012

Summary of Technological Characteristics

The Glytec, LLC Glucommander System described by this submission, contains a modification to the software. This modification is the addition of a pediatric protocol that considers the weight of the patient. Initial starting parameters and the user interface design were modified to allow for the easy identification and calculation of initial multiplier based on a pediatric patient's weight that clearly indicate the order set as either adult or pediatric. An additional input validation on the date of birth field identifies pediatric patients and calculates the patient's initial multiplier based on the patient's weight whereas the multiplier for the adult patients is still selected manually. In the adult protocol, the coefficient selection is unchanged.

Other user screen labeling such as the function of screen buttons, the ability to add additional patient data and user information, the ability to password protect information and other similar security features, data handling performance, user controlled automatic system shutdown and software update notifications are unchanged.

Statement of Substantial Equivalence

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

- GlyTec, LLC, G+ System #K101344 (6/28/2010)

Summary of Non Clinical Performance Data and Conclusions

The results of usability testing of representative users of the device, software testing and performance testing of the device demonstrate the device functions as intended.

Conclusion

Based upon an analysis of the performance characteristics of the Glytec, LLC, Glucommander System, Glytec, Inc. believes no differences exist between this system

and the predicate system that raise 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

Mr. William Matthews
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Glytec, LLC
770 Pelham Road, Suite 210
Greenville, South Carolina 29615

MAY - 8 2012

Re: K113853
Trade/Device Name: Glucommander™ System
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive Pulmonary-Function Value Calculator
Regulatory Class: II
Product Code: NDC
Dated: April 24, 2012
Received: April 26, 2012

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): K113853

Device Name: **Glucommander™ System**

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)

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

510(k) Number: K113853