DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 4, 2017

Glytec, LLC
Julie Glendrange
Sr. Director, Product Services and Regulatory Compliance
10 Patewood Drive, Suite 100
Greenville, SC 29615

Re: K152300
Trade/Device Name: Glytec Glucommander
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive Pulmonary-Function Value Calculator
Regulatory Class: Class II
Product Code: NDC
Dated: February 23, 2017
Received: February 24, 2017

Dear Julie Glendrange:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

James P. Bertram -S

for

Lori A. Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K152300

Device Name
Glytec Glucommander

Indications for Use *(Describe)*
The Glucommander System is a glycemic management tool intended to evaluate current as well as cumulative patient blood glucose values 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 physician-determined target range.

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

The G+ 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## 5. TRADITIONAL 510(K) SUMMARY

## K152300

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| **SUMMARY PREPARED ON:** | July 31, 2017 |
| **SUBMITTED BY:** | Glytec, LLC<br>10 Patewood Drive, Suite 100<br>Greenville, SC 29615<br>Phone: (864) 263-4180 |
| **CONTACT PERSON:** | Julie Glendrange<br>Glytec, LLC<br>10 Patewood Drive, Suite 100<br>Greenville, SC 29615<br>Phone: (864) 263-4180 |
| **DEVICE NAME:** | Glytec Glucommander |
| **COMMON NAME:** | Calculator, Drug Dose |
| **CLASSIFICATION:** | Class II, 21 CFR 868.1890 Predictive Pulmonary Function Value Calculator |
| **PRODUCT CODE:** | NDC |
| **SUBSTANTIALLY EQUIVALENT DEVICE:** | Glytec LLC Glucommander System (K113853, May 8, 2012) |
| **DEVICE DESCRIPTION:** | The Glucommander System is a software algorithm 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, recommend a dosage of insulin, glucose, or saline in order 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. |

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| **INDICATIONS FOR USE:** | The Glucommander System is a glycemic management tool intended to evaluate current as well as cumulative patient blood glucose values 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 physician-determined target range.<br><br>The Glucommander System is indicated for use in adult and pediatric (ages 2 – 17 years) patients.<br><br>The G+ 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.<br><br>The indications for use are identical to the predicate device. |
| **TECHNOLOGICAL CHARACTERISTICS:** | Glucommander is a software device. The software includes security features, software upgrades, data backup capabilities and technical support. All users have their own user names and passwords to protect access to the program. All upgrades are performed from Glytec support. Glucommander ensures that it has the latest security features and that it maintains the confidentiality, integrity and availability of all information according to the HIPAA privacy<br><br>This 510(k) submission evaluated new functionality as well as modifications to existing |

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| | features including: the Continuous Tube Feeding Module, which is designed to cover patient's receiving enteral nutrition; the Ambulatory Care Module, which is designed to provide recommendations for patients outside the hospital environment; and the Subcutaneous Module, which is designed for non-critical patients in the hospital.<br><br>These features do not raise different questions of safety or effectiveness. Non-clinical performance data was used to demonstrate that the device is substantially equivalent to the predicate device. |
| **PERFORMANCE DATA:** | The 510k submission included software, cybersecurity, and human factors documentation to demonstrate the performance of the device is substantially equivalent to the predicate. |
| **SUBSTANTIAL EQUIVALENCE:** | Information presented supports substantial equivalence of the Glucommander System to the predicate device. The proposed enhancements have the same indications for use, are similar in design, have the same fundamental scientific technology, and are tested the same way as the predicate device. As detailed in the submission, the subject device is as safe and as effective as the predicate device. |