510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K254102

B Applicant

Glytec, LLC

C Proprietary and Established Names

Glucommander

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
NDC	II	21 CFR 868.1890 - Predictive Pulmonary-Function Value Calculator	CH - Clinical Chemistry

E Purpose for Submission:

Modification to the Glucommander cleared under K152300 to

- Update cybersecurity controls.
- Establish a Pre-Determined Change Control Plan (PCCP) .

II Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

Glucommander 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.

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

Glucommander 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.

C Special Conditions for Use Statement(s):

- Terminal patients: Glucommander is not appropriate for use with patients having a life expectancy less than 48 hours.
- Organ preservation: Glucommander is not intended for use in the preservation of donor-after-brain-death (DBD) organs.
- Severe Insulin Resistance: Patients receiving insulin at more than 500 units/hr are assumed to be extremely insulin resistant by the system. Glucommander will flash a warning message indicating possible severe insulin resistance, instructing the healthcare professional to contact the attending provider for treatment of insulin resistance before resuming the program.
- Patients with a known insulin allergy: do not use.
- Pediatric patients less than 2 years of age: do not use.

III Device Description

Glucommander operates as a cloud-hosted clinical decision support software as a medical device. The software receives patient-specific inputs such as demographic information, glucose values, and prescribed treatment parameters. Data may be entered manually by the clinician or transferred electronically from connected hospital systems where configured.

Using these inputs, Glucommander applies a deterministic, rule-based algorithm to calculate recommended intravenous infusion rates or subcutaneous basal, bolus, and correction doses. The algorithm considers current and recent glucose values, insulin sensitivity, and prescriber defined parameters. Safety limits and clinical notifications are applied to each calculation to prevent excessive or unsafe dosing and to prompt clinical review when glucose values exceed defined thresholds.

Recommendations and alerts are displayed through a user interface for the clinician's review. All insulin administration is performed manually by the treating clinician, who may accept, modify, or disregard the software's recommendations based on clinical judgment. Glucommander does not autonomously deliver insulin or interface with any infusion device to control therapy.

When configured, Glucommander supports interoperability with hospital systems to streamline workflow, such as single sign-on (SSO) access from the electronic health record (EHR) or the transfer of patient context. If integrated data are unavailable or a network interruption occurs, clinicians can manually enter required data to continue operation safely.

Glucommander operates within a cloud-hosted environment that is managed and maintained by Glytec under its quality-management and change-control processes. Authorized clinical users access the application through encrypted web connections, typically via browser launch or single sign-on (SSO) from the electronic health record (EHR).

In the current configuration, all clinical logic, processing, and data storage occur within the Glytec-managed cloud environment. The hospital network provides authenticated user access and, where configured, limited data exchange with the Glytec Interface Engine through encrypted connections.

IV Substantial Equivalence Information:

A Predicate Device Name(s):

Glucommander

B Predicate 510(k) Number(s):

K152300

C Comparison with Predicate(s):

Device & Predicate Device(s):	K254102	K152300
Device Trade Name	Glucommander	Glucommander
General Device Characteristic Similarities		
Intended Use/Indications For Use	Glucommander 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. Glucommander is indicated for use in adult and pediatric (ages 2 – 17 years)	Same

	patients. Glucommander 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.	
General Device Characteristic Differences		
Cybersecurity controls	Updated to align with current FDA guidance	Best practice at time of clearance
Use Environment	Healthcare facility environment	Clinics, Hospitals

Predetermined Change Control Plan (PCCP): In addition to the similarities and differences between the candidate and predicate devices listed in the table above, the candidate device has an authorized PCCP for updates to dose calculation logic and settings, for expanding alert contents, for enhancing record keeping, for modernizing user interface, and for adding another data input source. See Section VI.C for more information.

V Standards/Guidance Documents Referenced:

- ANSI AAMI ISO 14971: 2019 Medical devices - Applications of risk management to medical devices.
- ANSI AAMI IEC 62304:2006/A1:2016 Medical device software - Software life cycle processes [Including Amendment 1 (2016)].
- AAMI TIR57:2016 Principles for medical device security - Risk management.
- AAMI TIR97:2019 Principles for medical device security - Postmarket risk management for device manufacturers.
- ANSI AAMI SW91:2018 Classification of defects in health software.
- ISO 15223-1 Fourth edition 2021-07 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
- ISO 20417 First edition 2021-04 Corrected version 2021-12 Medical devices - Information to be supplied by the manufacturer
- ANSI AAMI IEC 62366-1:2015+AMD1:2020 (Consolidated Text) Medical devices Part 1: Application of usability engineering to medical devices, including Amendment 1

VI Performance Characteristics:

A. Non-Clinical Performance

1. Software:
   The software documentation provided was determined to be adequate to support substantial equivalence. Software Verification and Validation were conducted per FDA's 2023 device software guidance, IEC 62304, and ISO 14971, and demonstrated that the implemented software functions conform to their specified requirements for their intended clinical use.

2. Cybersecurity:
   The cybersecurity documentation was provided per FDA's 2025 premarket cybersecurity guidance expectations for SPDF and TPLC documentation, and was determined to be adequate to support substantial equivalence. Cybersecurity verification for the device is complete and traceable across the threat-to-test chain for the evidence set claimed for the current release. Any open findings or partial evidence (if present) are documented with explicit remediation and retest requirements. Residual risk acceptability for associated threat scenarios remains contingent on completion of those actions. Lifecycle monitoring, vulnerability intake, and patch governance are managed under the manufacturer's QMS processes and will continue postmarket as part of TPLC commitments.

B. Clinical Studies:

Not applicable.

C. Other Supportive Device Performance Characteristics Data

3. Pre-Determined Change Control Plan (PCCP)

   The PCCP documents how the device will be modified to update the dose calculation logic and settings and to expand alert contents to reflect evolving clinical practice, to modernize the user interface and to enhance record keeping for improving user experience, and to add another input source to enhance data accessibility.

   The evaluation methods for validating each modification are described below:

Modifications	Ver.	Reg.	Retro.	Expert	Usab.	Cyber.	Acc.
Dose adjustment for nutrition	Yes	Yes	Yes	Yes			
Dose adjustment for insulin on board	Yes	Yes	Yes		Yes		
IV target range expansion	Yes	Yes		Yes			
IV dose configurability with override controls	Yes	Yes			Yes		
Potassium level monitoring and notification	Yes	Yes			Yes		
User Interface Modernization	Yes	Yes			Yes		Yes

Accessory Mobile Interface	Yes	Yes			Yes	Yes	

- Verification testing (Ver.) – Design verification testing (including algorithm/logic testing, configuration testing, boundary and threshold testing, and interface testing) will be conducted for each modification following prespecified procedures.
- Regression testing (Reg.) – Confirmatory testing demonstrating that the modification does not alter existing cleared device functionality when the module is inactive or in fallback.
- Retrospective Data Benchmarking (Retro.) – Retrospective application of the modification to historical de-identified patient episode data, comparing glycemic outcomes to baseline.
- Structured Expert Validation Study (Expert) – Blinded review of representative management scenarios by independent board-certified subject matter experts, evaluated against clinical standards.
- Human Factors / Usability Testing (Usab.) – Human factors and usability testing conducted per IEC 62366-1 and pre-defined usability SOPs.
- Cybersecurity testing (Cyber.) – Security testing will be conducted per the pre-defined SOPs.
- Accessibility Audit (Acc.) – Automated and manual audit against an internationally recognized set of digital accessibility standards.

- The pre-specified acceptance criteria include pass rates for the defined tests.
- Labeling and training updates will be developed and controlled under pre-defined SOPs.
- Final release and deployment will follow pre-defined SOPs.

VII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

VIII Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.