



510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY

I Background Information:

A 510(k) Number

K261939

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 Glucommander cleared under K254102 to incorporate additional modifications to the 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 secure 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.

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):

Glytec Glucommander

B Predicate 510(k) Number(s):

K254102

C Comparison with Predicate(s):

Device & Predicate Device(s):	K261939	K254102
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) patients. Glucommander logic is not a	Same

	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.	
Use Environment	Clinical/Hospital, for use by trained personnel for the management of blood glucose levels	Same
General Device Characteristic Differences		
PCCP	Revised PCCP expanding the scope of the anticipated modifications.	Limited scope PCCP

Pre-determined Change Control Plan (PCCP): The candidate device has an authorized PCCP for the following modifications that were cleared in the predicate device: dose adjustment for nutrition, dose adjustment for insulin on board, IV target range expansion, IV dose configurability with override controls, potassium level monitoring and notification, user interface modernization, and accessory mobile interface. Additional modifications authorized in this submission include the following: glucocorticoid supplemental dose adjustment, multivariate initial dosing refinement, diabetic ketoacidosis and hyperosmolar hyperglycemic state workflow, dialysis and renal impairment workflow, intraoperative management workflow, and IV insulin infusion trend awareness refinement. 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

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.

Cybersecurity

The cybersecurity documentation was provided per FDA's 2026 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 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

Pre-Determined Change Control Plan

The PCCP defines the modifications that may be made to Glucommander (algorithm enhancement, workflow and usability adaptations, and safety guardrails and clinical notifications), the modification protocol to be followed, and the impact assessment used to evaluate risk, benefit, and overall device performance. Modifications in the PCCP include:

1. Dose adjustment for nutrition – This modification changes the workflow by incorporating electronic health record-sourced nutritional data to standardize dosing adjustments. All recommendations require clinician review and confirmation prior to administration.
2. Dose adjustment for insulin on board – This modification introduces a method to account for recent insulin activity and applies a bounded adjustment to the correction dose. All recommendations require clinician review and confirmation prior to administration.
3. IV target range expansion – This modification adjusts the configurable IV target range parameter and adds a lower-bound advisory during IV insulin episodes where the configured target includes an elevated lower bound. All recommendations require clinician review and confirmation prior to administration
4. IV dose configurability with override controls – This modification provides a mechanism to make limited adjustments to the recommended IV dose for a single interval. All recommendations and adjusted doses require clinician review and confirmation prior to administration.
5. Potassium level monitoring and notification – This modification adds potassium notifications using existing laboratory results and predefined thresholds. All insulin administration decisions require clinician review and confirmation.
6. User interface modernization – This modification updates the visual presentation and navigation structure of the device to standardize how information is displayed without changing clinical content or behavior.
7. Accessory mobile interface – This modification provide a mobile access point that allows clinicians to perform glucose entry and recommendation confirmation steps using an institutional mobile device at the bedside.
8. Glucocorticoid supplemental dose adjustment – This modification performs the same calculation within the Glucommander system as a clinician when supplemental insulin is required during steroid use and is based on the recommendation from the American Diabetes Association, the Endocrine Society, and the Joint British Diabetes Societies. All recommendations require clinician review and confirmation prior to administration.
9. Multivariate initial dosing refinement – This modification establishes a multivariate framework in which patient-specific factors inform the device’s insulin dosing recommendations and provides advisories to the clinician. All dose recommendations reduce the aggressiveness of a recommendation or withhold it and do not increase a dose or rate beyond the standard, and an advisory use case changes no device behavior but rather provides a notification to the clinician. All recommendations require clinician review and confirmation prior to administration.
10. DKA and HHS workflow – This modification adds a condition-specific workflow for patients in DKA or HHS. For patients managed with IV insulin, this modification applies a phase-based glucose target. This modification also adds a subcutaneous management option for mild DKA.

11. Dialysis and renal impairment – This modification considers renal status and incorporates renal adjustment into the device using institution-configured values within device-enforced bounds. The insulin dose is adjusted based on most recent eGFR or serum creatinine, which maps to a renal impairment stage and proportional dose reduction. All recommendations require clinician review and confirmation prior to administration.
12. Intraoperative management – This modification allows the clinician to select the interoperative phase, and the system applies the interoperative logic to IV insulin management. Phase entry and exit are clinician-initiated, and the system does not auto-detect the intraoperative phase or auto-transition out of it. All recommendations require clinician review and confirmation prior to administration.
13. IV insulin infusion trend awareness refinement – This modification refines the trend-aware behavior or IV infusion recommendations through adjustment of the IV insulin multiplier. All recommendations require clinician review and confirmation prior to administration.

The evaluation methods for validating each modification are described below:

Modification	Ver.	Reg.	Retro.	Expert	Usab.	Cyber.	Acc.
Dose Adjustment for Nutrition	yes	yes	yes	yes	no	no	no
Dose Adjustment for Insulin on Board	yes	yes	yes	no	yes	no	no
IV Target Range Expansion	yes	yes	no	yes	no	no	no
IV Dose Configurability with Override Controls	yes	yes	no	no	yes	no	no
Potassium Level Monitoring and Notification	yes	yes	no	no	yes	no	no
User Interface Modernization	yes	yes	no	no	yes	no	yes
Accessory Mobile Interface	yes	yes	no	no	yes	yes	no
Glucocorticoid Supplemental Dose Adjustment	yes	yes	yes	yes	yes	no	no
Multivariate Initial Dosing Refinement	yes	yes	yes	yes	yes	no	no
DKA and HHS Workflow	yes	yes	yes	yes	yes	no	no
Dialysis and Renal Impairment	yes	yes	yes	yes	yes	no	no
Intraoperative Management	yes	yes	yes	yes	yes	no	no

IV Insulin Infusion Trend Awareness Refinement	yes	yes	yes	yes	yes	no	no
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- 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 (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 prespecified 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 complete and supports a substantial equivalence decision.