May 27, 2026

Glytec, LLC
Robby Booth
Official Correspondent
200 N Main St.
Greenville, South Carolina 29601

Re: K254102
Trade/Device Name: Glucommander
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive pulmonary-function value calculator
Regulatory Class: Class II
Product Code: NDC
Dated: December 12, 2025
Received: December 19, 2025

Dear Robby Booth:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an

established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JOSHUA BALSAM -S

Joshua M. Balsam, Ph.D.
Branch Chief
Division of Chemistry and
Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K254102

Please provide the device trade name(s).

Glucommander

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

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

510(k) #: K254102

510(k) Summary

Prepared on: 2026-05-20

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Glytec, LLC
Applicant Address	200 N Main St Greenville SC 29601 United States
Applicant Contact Telephone	864-363-4096
Applicant Contact	Mr. Robby Booth
Applicant Contact Email	rbooth@glytecsystems.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Glucommander
Common Name	Predictive pulmonary-function value calculator
Classification Name	Calculator, Drug Dose
Regulation Number	868.1890
Product Code(s)	NDC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K152300	Glytec Glucommander	NDC

Device Description Summary

21 CFR 807.92(a)(4)

Glucommander is a Software as a Medical Device (SaMD) that provides insulin dosing recommendations for the management of hospitalized patients requiring glycemic control. It evaluates current and cumulative blood glucose values, along with patient-specific parameters such as age, weight, and height, and recommends dosing adjustments to guide blood glucose toward a configurable, clinician-determined target range. Once the target range has been achieved, Glucommander continues to recommend titrations of insulin, glucose, or saline for intravenous (IV) use, and basal-bolus insulin dosing recommendations for subcutaneous (SubQ) use, in order to maintain glucose within the selected target range. Glucommander is indicated for use in adult and pediatric patients ages 2 years and older.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The Indications for Use are identical to the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

Glucommander v3.6.0.0 is substantially equivalent to the predicate device Glucommander (K152300) in intended use, indications for use, and technological characteristics. Both systems are glycemic management tools that evaluate blood glucose data plus patient-specific factors (e.g., age, weight, height) to recommend IV insulin/glucose/saline dosing or subcutaneous basal-bolus insulin, for adult and pediatric patients ages 2–17. The new device employs the same fundamental scientific technology as the predicate, including a deterministic, rule-based dosing algorithm, clinician-mediated confirmation of recommendations, established safety guardrails/alerts/timers, EHR integration, and a web-based client-server deployment model. Across functional categories (dose computation, algorithms, interface, data storage/analysis, alarms, operating description, and use environment) the devices match, and no significant algorithmic or core technological changes have been introduced since K152300. What has changed in the new device is limited and does not impact safety or effectiveness. The primary labeling-related update is the addition of a Predetermined Change Control Plan (PCCP), which clarifies future change management without altering the device's intended use, indications, or underlying technology. Other updates since the predicate clearance have been risk-neutral and confined to workflow adaptations, cybersecurity strengthening, interoperability/configuration consistency, routine software and infrastructure maintenance, user-interface refinements, and supporting documentation aligned with current FDA SaMD expectations. All such modifications were implemented under Glytec's Quality Management System with verification and validation, and they do not raise new questions of safety or effectiveness compared to the predicate.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Nonclinical performance testing for Glucommander v3.6.0.0 consisted of software verification and validation (V&V) activities and cybersecurity testing, conducted under Glytec's Quality Management System in accordance with 21 CFR 820.30 design controls. Testing was performed at the unit, integration, and system levels and included requirements-based functional testing, boundary and negative testing, regression testing against the predicate (K152300) baseline, risk-control verification, and cybersecurity testing. Cybersecurity verification included functional security control testing and independent third-party penetration testing. Bidirectional traceability was maintained between software requirements, design outputs, risk controls, and verification evidence.

Testing was conducted with reference to the following FDA-recognized consensus standards and FDA guidance documents:
- IEC 62304: Medical device software – Software life cycle processes
- ISO 14971: Application of risk management to medical devices
- IEC 62366-1: Application of usability engineering to medical devices
- ISO 13485: Medical devices – Quality management systems
- FDA Guidance: Content of Premarket Submissions for Device Software Functions (June 2023)
- FDA Guidance: Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions for Premarket Submissions (2023)
- FDA Guidance: Predetermined Change Control Plans for Medical Devices (2024)

All verification and validation acceptance criteria were met, and all identified cybersecurity threat scenarios were mitigated by verified security controls. No unresolved anomalies impact the safety or effectiveness of the device.

No new clinical testing was required to support this submission.

Nonclinical software verification and validation testing and cybersecurity testing demonstrate that Glucommander v3.6.0.0 performs as intended and meets all design, interoperability, safety, and cybersecurity requirements. The subject device maintains the same intended use, indications for use, fundamental scientific technology, dosing algorithm, and clinical workflow as the predicate device Glucommander (K152300). The changes introduced in this submission, routine software maintenance, guidance-aligned cybersecurity updates, workflow and user interface refinements, and the addition of a Predetermined Change Control Plan, do not alter the device's intended use, do not introduce new technological characteristics, and do not raise new questions of safety or effectiveness. Based on these results, Glucommander v3.6.0.0 is as safe and as effective as the predicate device and is substantially equivalent to Glucommander (K152300).