June 12, 2026

Dexcom, Inc.
Shaun Adriano
Staff Regulatory Affairs Specialist
6340 Sequence Dr.
San Diego, California 92121

Re: K260935
Trade/Device Name: Stelo Glucose Biosensor System
Regulation Number: 21 CFR 862.1355
Regulation Name: Integrated continuous glucose monitoring system
Regulatory Class: Class II
Product Code: SBH
Dated: March 19, 2026
Received: March 20, 2026

Dear Shaun Adriano:

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.

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
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260935

Device Name
Stelo Glucose Biosensor System

Indications for Use *(Describe)*
The Stelo Glucose Biosensor System is an over-the-counter (OTC) integrated Continuous Glucose Monitor (iCGM) intended to continuously measure, record, analyze, and display glucose values in people 2 years and older not on insulin. The Stelo Glucose Biosensor System helps to detect normal (euglycemic) and low or high (dysglycemic) glucose levels. The Stelo Glucose Biosensor System may also help the user better understand how lifestyle and behavior modification, including diet and exercise, impact glucose excursion.

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.

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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The Assigned 510(k) number is: K260935
Prepared on: 2026-05-28

Contact Details

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Correspondent Contact	Shaun Adriano
Correspondent Contact Email	sadriano@dexcom.com

Device Name and Classification

Device Trade Name	Stelo Glucose Biosensor System
Common Name	Integrated Continuous Glucose Monitoring System
Classification Name	Integrated Continuous Glucose Monitoring System, Factory Calibrated
Regulation Number	21 CFR 862.1355
Product Code	SBH

Legally Marketed Predicate Device:

Predicate #	K234070
Predicate Trade Name	Stelo Glucose Biosensor System
Product Code	SAF

Legally Marketed Reference Devices:

Reference #	K213919
Reference Trade Name	Dexcom G7 Continuous Glucose Monitoring System
Product Code	QBJ

Reference #	K234133
Reference Trade Name	Dexcom G7 Continuous Glucose Monitoring System
Product Code	QBJ

Reference #	K243214
Reference Trade Name	Dexcom G7 15 Day Continuous Glucose Monitoring System
Product Code	QBJ

Device Description Summary:

The Stelo Glucose Biosensor system (Stelo System) is an over-the-counter (OTC) interoperable continuous glucose monitoring (iCGM) system intended to continuously measure the glucose in the interstitial fluid, calculate the glucose reading and make this available to the user. The Stelo System is intended for single-user home use.

The Stelo System is for people who do not use insulin, ages 2 years and older (caregiver supervision required for those under 18). The Stelo System is not for people on dialysis, with problematic hypoglycemia, are modifying medication without HCP consultation, or have a history of eating disorders.

The Stelo Glucose Biosensor system (Stelo System) is an interoperable connected device that measures and displays estimated glucose values for people who are not on insulin. The Stelo System consists of the following components: the Glucose Sensing Subsystem (GSS) and the display device. The display device is a Mobile Application (Mobile App) on an iOS or Android OS smart device. The GSS is comprised of the sensor applicator and on-body wearable, which includes a Bluetooth Low Energy (BLE) molded transmitter, adhesive patch and sensor.

To achieve the intended functions and performance of the Stelo System, the sensor and display device must be used together. The user must pair the display device with each unique sensor to enable communication and start a sensor session. During an active session, the sensor reports new glucose data to the display device every 5 minutes. The display device then displays glucose data to the user every 15 minutes. The reportable glucose range for the Stelo System is 55 mg/dL to 350 mg/dL. The display device user interface will inform the user if they are above or below reportable range. The display device does not provide any glucose alerts. The sensor has an expected wear period of up to 15 days with an extended 12-hour grace period after the sensor session. The grace period allows additional time for the user to change the sensor at a convenient time.

The Stelo System is an interoperable connected device that can communicate glucose readings and other information wirelessly and securely to and from compatible electronic interfaces via the following secure wireless connections:

- Wireless communication from the transmitter directly to an interoperable device communicating through the same protocol
- The app communicates to another app on a single mobile platform
- The app communicates through the cloud to another software device

Principle of Operation:

The principles of operation for the Stelo System remain the same as the predicate. The System uses a wire-type sensing mechanism that continuously measures interstitial glucose levels and uses a radio transmitter to wirelessly communicate glucose data to the display device for the user to see and use accordingly.

Intended Use/Indications for Use

Stelo Glucose Biosensor System:

The Stelo Glucose Biosensor System is an over-the-counter (OTC) integrated Continuous Glucose Monitor (iCGM) intended to continuously measure, record, analyze, and display glucose values in people 2 years and older not on insulin. The Stelo Glucose Biosensor System helps to detect normal (euglycemic) and low or high (dysglycemic) glucose levels. The Stelo Glucose Biosensor System may also help the user better understand how lifestyle and behavior modification, including diet and exercise, impact glucose excursion.

Indications for Use Comparison

The differences between the indications for use of the predicate device (K234070) and subject device (Stelo Glucose Biosensor System) are related to the age of the patient population – the subject device is indicated for persons not on insulin age 2 years and older, whereas the predicate device is indicated for persons not on insulin age 18 years and older. The subject device also removes the statement "The user is not intended to take medical action based on the device output without consultation with a qualified healthcare professional" when compared to the predicate device. The differences are not critical to the intended use of the device for managing a disease or condition related to glycemic control.

Technological Comparison

The subject device has the same fundamental technological characteristics as the predicate device (K234070). The subject device introduces the capability for the Stelo System to display glucose data directly from the transmitter on compatible watchOS smartwatches and an expanded glucose display range on the primary display device. Design differences between the subject device and the predicate device does not constitute a new intended use. The subject device is as safe and effective as the predicate device and does not raise different questions of safety and effectiveness.

Non-Clinical and/or Clinical Tests Summary and Conclusions

The supportive performance characteristics listed below were established through nonclinical testing of the predicate device (K234070) or reference devices (K243214, K234133, K213919) and are applicable to the subject Stelo Glucose Biosensor System (Stelo System) in this 510(k):

- Biocompatibility
- Chemical/Material Characterization (not Biocompatibility-related)
- Sterilization Validation
- Interoperability
- Packaging Validation
- Operating Environmental Conditions Testing
- Electrical and Mechanical Performance
- Electromagnetic Compatibility and Wireless Coexistence testing
  This testing demonstrates that the electromagnetic compatibility and wireless coexistence performance characteristics of the Stelo Glucose Biosensor System are not impacted by the Direct-to-watch (DTW) feature.
- Communication Range testing
  This testing demonstrates that the Stelo watchOS App with DTW feature has the same communication range as the Stelo Mobile App.
- Human Factors
  This testing demonstrates that the Stelo System is safe and effective for the intended user population in the intended use environments.

The following performance characteristics were verified or validated through studies conducted on the subject device, Stelo System:

- Operating Environmental Conditions Testing (Shelf-life testing):
  Shelf-life testing was performed to evaluate the stability of Stelo Glucose Sensing Subsystem under real time anticipated storage conditions and supported its useful life to be up to 18 months. The test results for the Stelo Glucose Sensing Subsystem met specifications.
- Software Verification and Validation:
  Software verification and validation testing was conducted to confirm that the software used in the Stelo System performed in accordance with established specifications, IEC

62304 and FDA Guidance document "*Guidance for the Content of Premarket Submissions for Device Software Functions*," June 14, 2023. Evaluation activities included code review, unit, system integration, and system level testing which verified functionality of the device against established software requirements. Results of the software executed protocols for the Stelo System are acceptable for their intended use.

- Cybersecurity:
  Dexcom has provided cybersecurity risk management documentation for the Stelo System that includes analysis of confidentiality, integrity, and availability for data, information and software related to the Stelo System in accordance with the FDA Guidance "*Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*" (June 27, 2025). For each identified threat and vulnerability risk event scenario, risk assessment of impact to confidentiality, integrity, and availability was performed and documented within the cybersecurity risk management documentation. Appropriate risk mitigation controls have been implemented and tested. In addition, Dexcom has controls and processes in place to ensure continued support for keeping the device secure and to ensure that the device firmware, software and components are malware free. Additional controls are also in place in manufacturing through distribution to ensure that the medical device firmware and software are malware free from point of origin to the hands of the end user.
- Interoperability (display device software interoperability testing):
  Software Verification and Validation of the Stelo System through system integration and system level testing was performed on the subject device to ensure the Stelo System and its interoperable functions perform in accordance with established specifications, IEC 62304, FDA Guidance document "*Guidance for the Content of Premarket Submissions for Device Software Functions*," June 14, 2023, and FDA Guidance document "*Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices*," September 6, 2017. Results of the software executed protocols for the Stelo System and its interoperable functions are acceptable for their intended use.

The clinical evidence provided in this 510(k) submission is summarized in the following discussion:

The analysis of a previously completed clinical study was performed to support the safety and effectiveness of the Stelo Glucose Biosensor System in pediatric users (ages 2-17) for wear days 1-10. In the study, the effectiveness of the device was evaluated with respect to reference venous plasma sample YSI measurements for ages 7 to 17 years of age, and reference capillary sample blood glucose measurements for ages 2 to 6 years of age, across the measuring range throughout a 10-day wear duration with a 12-hour grace period. The data from these devices were re-processed using the Stelo algorithm. As part of the analysis, pediatric accuracy performance was evaluated and compared with adults across glucose ranges and across the wear period. Similarly, pediatric survival performance was evaluated and compared with adults. The safety of the device was evaluated by the incidence of device-related adverse events (AEs) experienced by study subjects. The reported device-related AEs included local infection, skin irritation (edema), and pain or discomfort.

The analysis demonstrated that the Stelo Glucose Biosensor System in pediatrics is safe and effective for its intended use and demonstrates the subject device meets the

applicable iCGM special controls for clinical performance set forth in 21 CFR 862.1355 for wear days 1-10.

While sensor survival and accuracy for pediatrics (ages 2-17) on days 11-15 have not been directly assessed in a clinical study, based on design of the Stelo Glucose Biosensor System and available performance data from the G7 10-day and Stelo systems, it is reasonable to expect that pediatric sensor accuracy may be comparable to adult sensor accuracy, and pediatric sensor survival is likely lower than adult survival.

A separate evaluation was performed to assess the data transmission reliability of the Stelo System with included DTW interface over the 15-day wear period. The results from the evaluation demonstrate the reliable data transmission rate to connected devices.

Nonclinical testing results demonstrate that the Stelo Glucose Biosensor System meets pre-defined acceptance criteria and supports that the device is acceptable for its intended use. Clinical evidence demonstrates that the Stelo Glucose Biosensor System meets the iCGM special controls for clinical performance set forth in 21 CFR 862.1355. The clinical data of the Stelo Glucose Biosensor System were also compared to that of the predicate device to support a substantial equivalence decision.