May 21, 2026

Dexcom, Inc.
Anthony Hardcastle
Staff Regulatory Affairs Specialist
6340 Sequence Dr.
San Diego, California 92121

Re: K261359
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: SAF
Dated: April 24, 2026
Received: April 24, 2026

Dear Anthony Hardcastle:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the Medical Device File (21 CFR 820.181).

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
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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)*
K261359

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 18 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.

The user is not intended to take medical action based on the device output without consultation with a qualified healthcare professional.

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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Dexcom, Inc. | Corporate Headquarters
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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: K261359
Prepared on: 2026-04-22
The 510(k) number is not yet assigned. This is a new submission.

Contact Details

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Correspondent Contact	Anthony Hardcastle
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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	SAF

Legally Marketed Predicate Devices:

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

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 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 70 mg/dL to 250 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 Mobile Application communicates to another app on a single mobile platform.
- The Mobile Application 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 18 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.

The user is not intended to take medical action based on the device output without consultation with a qualified healthcare professional.

Indications for Use Comparison

The indications for use are the same for the subject device and the predicate device (K234070).

Technological Comparison

The subject device has the same fundamental technological characteristics as the predicate device (K234070). The subject device introduces changes to the Mobile App user interface intended to increase user visibility into metabolic health through lifestyle-related informational features, including glucose response scores and expanded access to historical glucose and event data and related metrics. 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 following performance characteristics were verified or validated through studies conducted on the subject device, Stelo System:

- 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, software verification, 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*" (Feb 3, 2026). 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.

Non-clinical testing demonstrated that the Stelo System met all pre-defined acceptance criteria and is suitable for its intended use. These non-clinical data support a determination of substantial equivalence.