August 11, 2026

Dexcom, Inc.
Uday Sandilya Bhagavatula
Staff Specialist, Regulatory Affairs
6340 Sequence Dr.
San Diego, California 92121

Re: K262472
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: July 17, 2026
Received: July 17, 2026

Dear Uday Sandilya Bhagavatula:

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
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.	
Please provide the device trade name(s).	Stelo Glucose Biosensor System
Please provide your Indications for Use below.	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.
Please select the types of uses.	☐ Prescription Use (21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☒ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

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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: K262472
Prepared on: 2026-08-07

Contact Details

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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 Monitor For Non-Intensive Glucose Management, Over-The-Counter
Regulation Number	21 CFR 862.1355
Product Code	SBH

Legally Marketed Predicate Devices:

Predicate #	K260935
Predicate Trade Name	Stelo Glucose Biosensor System
Product Code	SBH

Legally Marketed Reference Devices:

Predicate #	K253737
Predicate Trade Name	Dexcom G7 Continuous Glucose Monitoring System
Product Code	QBJ

Predicate #	K253737
Predicate 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 interoperable continuous glucose monitoring system (CGM). Same as the predicate (K260935), the Stelo System is intended to continuously measure the glucose in the interstitial fluid, calculate the glucose reading and make this value available to the user. The Stelo System can reliably and securely transmit glucose measurement data to authorized digitally connected devices via the following secure wireless connections:

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

The subject device is indicated for adults aged 2 years and older not on insulin. The system is intended for home use and is offered as an over the counter (OTC) device.

The Stelo System has the same principle of operation, fundamental design, and physical characteristics as the predicate device. The Stelo system consists of the following primary components: a wearable, consisting of a sensor and transmitter worn on the body and one or more receiving devices that act as primary display devices, consisting of the Stelo Mobile Application (Mobile App) on an iOS or Android smart device and for users with compatible Apple iPhone and Apple Watch devices, the Stelo iOS Watch App via the Direct to Watch (DTW) feature when enabled by the user,

The Stelo System uses Bluetooth Low Energy (BLE) for wireless communication between these components. The user must pair the receiving 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 receiving device (s), including the Mobile App and, when enabled, the Watch App, every 5 minutes. The receiving device then displays and updates glucose data to the user every 15 minutes. The reportable glucose range for the Stelo System is 55 mg/dL to 350 mg/dL. Glucose values below this range are reported as 'Below 55' and glucose values above this range are reported as 'Above 350'. 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.

Principle of Operation:

The principles of operation for the Stelo System remain the same as predicate. The Stelo System detects glucose levels from the fluid just beneath the skin (interstitial fluid). The sensor probe continuously measures glucose concentration in the interstitial fluid via an enzymatic electrochemical reaction using glucose oxidase. The enzyme, glucose oxidase, catalyzes the oxidation of glucose and produces hydrogen peroxide. The production of hydrogen peroxide generates an electrical current that is proportionate to the interstitial glucose concentration. The transmitter converts the signal using an algorithm to a glucose value read in mg/dL, which is then transmitted to the mobile application for the user to see and use accordingly.

Intended Use/Indications for Use

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 indications for use is the same for the subject device (Stelo Glucose Biosensor System) and the predicate device (K260935).

Technological Comparison

The subject device (Stelo Glucose Biosensor System) has the same fundamental technological characteristics as the predicate device (K260935). The subject device introduces an alternate adhesive patch on the wearable. Design differences between the subject device and the predicate device do 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 or effectiveness.

Non-Clinical and/or Clinical Tests Summary and Conclusions

The following performance characteristics were verified or validated through studies conducted on the previously cleared reference devices (Dexcom G7 CGM System and Dexcom G7 15 Day CGM System), and are applicable to the subject Stelo System:

- Biocompatibility:
  Dexcom conducted biocompatibility testing in accordance with ISO 10993
- Sterilization:
  Dexcom conducted a sterilization assessment in accordance with AAMI TIR 28 and ANSI/AAMI/ISO 11135
- Shelf life:
  Dexcom conducted functional testing following accelerated aging conditioning
- Physical and Mechanical Characterization:

  Dexcom conducted mechanical functional testing to verify the alternate adhesive patch is suitable for its intended use.
- Clinical study:

  Dexcom conducted a clinical study to validate that the CGM System with the alternate adhesive patch can be used safely and effectively as intended by the intended users

Nonclinical and clinical testing results conducted on the previously cleared Dexcom G7 CGM System and Dexcom G7 15 Day CGM System demonstrates that the Stelo Glucose Biosensor System meets pre-defined acceptance criteria and support that the subject device is acceptable for its intended use. The clinical and nonclinical evidence used to demonstrate substantial equivalence of the alternate adhesive patch for the G7 System is directly applicable to the subject Stelo System. Accordingly, the available nonclinical and clinical data support a determination that the alternate adhesive patch configuration for the Stelo System is substantially equivalent to the predicate device.