March 5, 2024

Dexcom, Inc.
Maryam Amini
Sr. Manager, Regulatory Affairs
6340 Sequence Drive
San Diego, California 92121

Re: K234070
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: December 21, 2023
Received: December 22, 2023

Dear Maryam Amini:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (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 systems (QS) regulation (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.

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
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OHT7: Office of In Vitro Diagnostics
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K234070

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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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: K234070
Prepared on: 2024-03-05

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 monitoring, Over-The-Counter
Regulation Number	862.1355
Product Code(s)	SAF

LEGALLY MARKETED PREDICATE DEVICES

Predicate #	K231081
Predicate Trade Name	Dexcom G7 Continuous Glucose Monitoring System
Product Code	QBJ

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Device Description Summary

The Stelo Glucose Biosensor system (Stelo System) is an over-the-counter (OTC) interoperable continuous glucose monitoring (iCGM) system.

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 Mobile Application Subsystem (MAS). 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. The sensor is a small and flexible wire, which is inserted by the applicator into subcutaneous tissue where it converts glucose into electrical current. The transmitter's onboard algorithm converts these measurements into estimated glucose values and calculates the glucose rate of change which are sent every 5 minutes to the MAS. The MAS is an app that can be downloaded to a compatible smart device and that presents glucose readings and glucose trend to the user every 15 minutes. As such, the most recent displayed glucose value might be up to 15 minutes old. Each sensor session lasts up to 15 days with an extended 12-hour grace period. The grace period allows additional time for the user to change the sensor at a convenient time.

The proposed Stelo System is based on the same mode of operation and mechanism of reaction as the predicate G7 CGM System (K231081), which uses a wire type sensing mechanism that continuously measures interstitial fluid glucose levels and a BLE enabled radio transmitter to wirelessly communicate CGM data to compatible display devices at regular 5-minute intervals. These data are also able to be reliably and securely transmitted to other digitally connected devices, excluding insulin devices such as insulin pens and Automated Insulin Dosing (AID) systems.

The Stelo System uses the same hardware design as the predicate G7 CGM System. The Stelo GSS firmware is designed to support a factory-calibrated only device (without calibration inputs), to extend the sensor wear duration from 10 to 15 days while maintaining the accuracy of the device, and to connect to authorized display devices only (i.e., Stelo MAS). The Stelo MAS includes a redesigned user interface (UI) tailored to the Stelo System's user population to simplify the use of the device. The UI includes an app onboarding specific to the Stelo MAS design and its intended use, the most recent glucose value and trend graph which are updated every 15 minutes, a narrowed glucose range display from 70 mg/dL to 250 mg/dL, and an "Insights" feature providing the time in range percentage with suggestions to help users improve their time in range. The UI does not provide any glucose or system alerts.

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 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 differences between the indications for use of the predicate (G7 CGM System) and subject (Stelo Glucose Biosensor System) devices are not critical to the intended use of the device for managing a disease or condition related to glycemic control.

Technological Comparison

The Stelo System shares identical hardware, material, chemical composition, principle of operation and energy source with the predicate device. Design differences between the Stelo Glucose Biosensor System and the predicate device does not constitute a new intended use. The Stelo Glucose Biosensor System 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 supportive performance characteristics were established through nonclinical testing of the predicate device and are applicable to the Stelo Glucose Biosensor System in this 510(k):

- Biocompatibility
- Chemical/Material Characterization (not Biocompatibility-related)
- Sterilization Validation
- Electrical and Mechanical Performance
- Operating Environmental Conditions Testing
- Wireless Coexistence
- Electrical Safety and Electromagnetic Compatibility
- Packaging Validation
- Interoperability

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

- Electrical and Mechanical Performance (session dependent testing):
  Performance testing was performed to ensure the device specifications for sensor sensitivity, linearity, and fatigue, as well as wearable battery life and current leakage were met.
- Operating Environmental Conditions Testing:
  Environmental testing was performed on the Stelo Glucose Biosensor System to ensure the device specifications for operational robustness, operating conditions (evaluation of performance under various operational temperatures and humidity conditions), and chemical robustness (evaluation of performance when subject to soap water) were met.
- Shelf-Life:
  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 10 months. The test results for the Stelo Glucose Sensing Subsystem met specifications.

- Human Factors:
  Human factors and usability testing of the Stelo Glucose Biosensor System was conducted to determine whether users can appropriately self-identify themselves as appropriate users using the information on the device's pre-purchase labeling and whether the intended user population can safely use the system under representative conditions. Human factors testing was conducted in accordance with:

  - Design considerations for Devices intended for Home Use, Guidance to FDA Staff and Industry, November 24, 2014
  - Applying Human Factors and Usability Engineering to Medical Devices, Guidance to FDA Staff and Industry, February 3, 2016
  - IEC 62366-1:2015/AMD 1:2020: Medical devices – Part 1: Application of Usability Engineering to Medical Devices
  - ANSI/AAMI HE75:2009/(R) 2018 – Human Factors Engineer, Design of Medical Devices

  The critical, essential and frequently performed tasks were evaluated to demonstrate safe and effective use of the Stelo System and were identified through a use-related risk analysis (URRA), which identified critical tasks solely based on the Severity of harm and included tasks resulting from known-use problems and hazards analysis. An analysis of hazards and risks was conducted on the Stelo Glucose Biosensor System to determine safety risks associated with use of the system. Results of the human factors study support that the general population (lay users) can correctly self-identify themselves as appropriate users and that the intended users can use the Stelo Glucose Biosensor System safely and effectively.

- Software Verification and Validation:
  Software verification and validation testing was conducted to confirm that the software used in the Stelo Glucose Biosensor 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 Glucose Biosensor System are acceptable for their intended use.

- Cybersecurity:
  Dexcom has provided cybersecurity risk management documentation for the Stelo Glucose Biosensor System that includes analysis of confidentiality, integrity, and availability for data, information and software related to the Stelo Glucose Biosensor System in accordance with the FDA Guidance Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" (September 27, 2023). 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.

A clinical study was conducted to evaluate the safety and effectiveness of the Stelo Glucose Biosensor System. The effectiveness of the device was evaluated with respect to reference venous plasma sample YSI measurements across the measuring range throughout a 15-day wear duration with a 12-hour grace period in

adult (18 years and older) participants with diabetes. Analysis of the results from the clinical studies show that the subject device meets the iCGM special controls for clinical performance set forth in 21 CFR 862.1355. 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 clinical study demonstrated that the Stelo Glucose Biosensor System is safe and effective for its intended use.

Nonclinical testing results demonstrate that the Stelo Glucose Biosensor System meets pre-defined acceptance criteria and support that the device is acceptable for its intended use. Clinical study results demonstrate 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.