FDA 510(k) Premarket Notification

K261359 Stelo Glucose Biosensor System

CLEARED

May 21, 2026
27 days to decision

K261359 · Product code: **SAF** · Chemistry
Source: https://www.510kdatabase.net/k261359/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Integrated Continuous Glucose Monitor For Non-intensive Glucose Monitoring, Over-the-counter (SAF)
Date received	Apr 24, 2026
Decision date	May 21, 2026
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Dexcom, Inc.**
Location	San Diego, CA, US
Contact	Ginny Hu
Website	https://www.dexcom.com
510(k) history	25 submissions · 22 cleared · 2014-2026

Dexcom, Inc. is a medical device company headquartered in San Diego, US. The company specializes in continuous glucose monitoring systems and related chemistry devices. Dexcom has received FDA 510(k) clearances from total submissions since its first clearance in 2014. The company's regulatory portfolio is dominated by chemistry devices, which account for 92% of submissions. The latest clearance was granted in 2026, reflecting active ongoing development and regulatory engagement. The company's cleared device portfolio centers on continuous glucose monitoring technology. Re...

CLINICAL EVIDENCE - NCT04794478

Evaluation of the Safety and Effectiveness of the Dexcom Continuous Glucose Monitoring (CGM) System

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	482 patients (actual)
Study sites	12 sites
Condition studied	Diabetes Mellitus
Primary purpose	Other
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Oct 31, 2021
Sponsor	DexCom, Inc. (Industry)

Primary outcome

Dexcom Continuous Glucose Monitoring System Performance

Secondary outcome

System Related Adverse Device Effects

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04794478