FDA 510(k) Premarket Notification

CLEARED

K234070 Stelo Glucose Biosensor System

Mar 5, 2024
74 days to decision

K234070 · Product code: **SAF** · Chemistry
Source: https://www.510kdatabase.net/k234070/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Integrated Continuous Glucose Monitor For Non-intensive Glucose Monitoring, Over-the-counter (SAF)
Date received	Dec 22, 2023
Decision date	Mar 5, 2024
Days to decision	74 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Dexcom, Inc.**
Location	San Diego, CA, US
Contact	Neeta Sharma
Website	https://www.dexcom.com
510(k) history	24 submissions · 21 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 - NCT05263258

[Trial of device that is not approved or cleared by the U.S. FDA]

Status	Withheld - *No results published to ClinicalTrials.gov*
Sponsor	[Redacted]

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05263258