FDA 510(k) Premarket Notification

CLEARED

K213919 Dexcom G7 Continuous Glucose Monitoring System

Dec 7, 2022
357 days to decision

K213919 · Product code: **QBJ** · Chemistry
Source: https://www.510kdatabase.net/k213919/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Integrated Continuous Glucose Monitoring System, Factory Calibrated (QBJ)
Date received	Dec 15, 2021
Decision date	Dec 7, 2022
Days to decision	357 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...