FDA 510(k) Premarket Notification

CLEARED

K193642 Dexcom G6 Glucose Program Continuous Glucose Monitoring (CGM) System

Jan 29, 2020
30 days to decision

K193642 · Product code: **QDK** · Chemistry
Source: https://www.510kdatabase.net/k193642/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Integrated Continuous Glucose Monitoring System For Non-intensive Diabetes Management (QDK)
Date received	Dec 30, 2019
Decision date	Jan 29, 2020
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Dexcom, Inc.**
Location	San Diego, CA, US
Contact	Linda Wang
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...