

K200876 Dexcom G6 Continuous Glucose Monitoring System, Dexcom G6 Glucose Program Continuous Glucose Monitoring System

Dec 4, 2020
247 days to decision

K200876 · Product code: **QBJ** · Chemistry
Source: <https://www.510kdatabase.net/k200876/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Integrated Continuous Glucose Monitoring System, Factory Calibrated (QBJ)
Date received	Apr 1, 2020
Decision date	Dec 4, 2020
Days to decision	247 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dexcom, Inc.
Location	San Diego, CA, US
Contact	Maryam Amini
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...