

K191450 Dexcom G6 Continuous Glucose Monitoring System, Dexcom G6 Glucose Program Continuous Glucose Monitoring System and Dexcom Pro Q Continuous Glucose Monitoring System

Jun 28, 2019
28 days to decision

K191450 · Product code: **QBJ** · Chemistry
Source: <https://www.510kdatabase.net/k191450/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Integrated Continuous Glucose Monitoring System, Factory Calibrated (QBJ)
Date received	May 31, 2019
Decision date	Jun 28, 2019
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dexcom, Inc.
Location	San Diego, CA, US
Contact	Emily Chung
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...