

K171450 Glooko Mobile Insulin Dosing SystemFeb 2, 2018
261 days to decisionK171450 · Product code: **NDC** · General Hospital
Source: <https://www.510kdatabase.net/k171450/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calculator, Drug Dose (NDC)
Date received	May 17, 2017
Decision date	Feb 2, 2018
Days to decision	261 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Glooko, Inc.
Location	Palo Alto, CA, US
Contact	Tejasvi Pasi
Website	https://www.glooko.com
510(k) history	5 submissions · 5 cleared · 2012-2026

Glooko, Inc. is a digital health company specializing in diabetes management and remote patient monitoring. Based in Palo Alto, California, the company develops integrated platforms that connect patients, healthcare providers, and medical devices to streamline diabetes data collection and clinical oversight. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2012. Chemistry devices represent the dominant category, accounting for approximately 80% of submissions. The most recent clearance was issued in 2026, confirming active...

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