FDA 510(k) Premarket Notification

CLEARED

K130886 GLOOKO DEVICE SYSTEM FOR GLOOKO LOGBOOK+ APPLICATION

Apr 25, 2013
27 days to decision

K130886 · Product code: **NBW** · Chemistry
Source: https://www.510kdatabase.net/k130886/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Mar 29, 2013
Decision date	Apr 25, 2013
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Glooko, Inc.**
Location	Palo Alto, CA, US
Contact	SHILPA MYDUR
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...