

K260910 EndoTool IV Cloud 1.0May 1, 2026
43 days to decisionK260910 · Product code: **NDC** · Chemistry
Source: <https://www.510kdatabase.net/k260910/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calculator, Drug Dose (NDC)
Date received	Mar 19, 2026
Decision date	May 1, 2026
Days to decision	43 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Glooko, Inc.
Location	Palo Alto, CA, US
Contact	Katherine Rojas
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...