

K254102 GlucommanderMay 27, 2026
159 days to decisionK254102 · Product code: **NDC** · Chemistry
Source: <https://www.510kdatabase.net/k254102/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calculator, Drug Dose (NDC)
Date received	Dec 19, 2025
Decision date	May 27, 2026
Days to decision	159 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

Company	Glytec, LLC
Location	Greenville, SC, US
Contact	Robby Booth
510(k) history	3 submissions · 3 cleared · 2012-2026

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