

K252104 T1D1Aug 20, 2025
48 days to decisionK252104 · Product code: **NDC** · Chemistry
Source: <https://www.510kdatabase.net/k252104/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calculator, Drug Dose (NDC)
Date received	Jul 3, 2025
Decision date	Aug 20, 2025
Days to decision	48 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Comerge AG
Location	Zurich, CH
Contact	Andreas Pedroni
510(k) history	2 submissions · 2 cleared · 2024-2025

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