

K253281 UpDoc

Dec 23, 2025
85 days to decision

K253281 · Product code: **NDC** · Chemistry
Source: <https://www.510kdatabase.net/k253281/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calculator, Drug Dose (NDC)
Date received	Sep 29, 2025
Decision date	Dec 23, 2025
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

Company	Updoc, Inc.
Location	Mountain View, CA, US
Contact	Kendal Dinsmore
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	RQM+
Contact	Erin Gontang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)
