

K202596 Insulia Diabetes Management CompanionJun 4, 2021
269 days to decisionK202596 · Product code: **NDC** · Chemistry
Source: <https://www.510kdatabase.net/k202596/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Calculator, Drug Dose (NDC)
Date received	Sep 8, 2020
Decision date	Jun 4, 2021
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Voluntis Sa.
Location	Paris, FR
Contact	Kevin Howard
510(k) history	5 submissions · 5 cleared · 2016-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202596/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026