

**K161433 Insulia Diabetes Management Companion**Nov 9, 2016  
169 days to decisionK161433 · Product code: **NDC** · General Hospital  
Source: <https://www.510kdatabase.net/k161433/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calculator, Drug Dose (NDC)
Date received	May 24, 2016
Decision date	Nov 9, 2016
Days to decision	169 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Voluntis Sa.</b>
Location	Paris, FR
Contact	RAFFI KRIKORIAN
510(k) history	5 submissions · 5 cleared · 2016-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161433/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026