

K160199 Advocate Insulin Pen NeedlesOct 19, 2016
265 days to decisionK160199 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k160199/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jan 28, 2016
Decision date	Oct 19, 2016
Days to decision	265 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Diabetic Supply of Suncoast, Inc.
Location	Dorado, PR, US
Contact	Victoria Thuss
510(k) history	1 submissions · 1 cleared · 2016-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k160199/> 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 June 2, 2026