

K202279 Insignis Subcutaneous Needle SetsAug 13, 2021
367 days to decisionK202279 · Product code: **FPA** · General HospitalSource: <https://www.510kdatabase.net/k202279/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Aug 11, 2020
Decision date	Aug 13, 2021
Days to decision	367 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Innovative Health Sciences, LLC
Location	Chester, NY, US
Contact	Andy Sealfon
510(k) history	2 submissions · 2 cleared · 2021-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202279/> 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