

K213089 Ivenix Infusion System, LVP Epidural Administration Set NRFit ConnectorNov 10, 2021
47 days to decisionK213089 · Product code: **FPA** · General Hospital
Source: <https://www.510kdatabase.net/k213089/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Set, Administration, Intravascular (FPA)
Date received	Sep 24, 2021
Decision date	Nov 10, 2021
Days to decision	47 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ivenix, Inc.
Location	North Andover, MA, US
Contact	John Sokolowski
510(k) history	2 submissions · 2 cleared · 2019-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213089/> 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