FDA 510(k) Premarket Notification

K261530 iiSure Infusion Set

CLEARED

Jun 3, 2026
26 days to decision

K261530 · Product code: **FPA** · Chemistry
Source: https://www.510kdatabase.net/k261530/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Set, Administration, Intravascular (FPA)
Date received	May 8, 2026
Decision date	Jun 3, 2026
Days to decision	26 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Deka Research and Development**
Location	Manchester, NH, US
Contact	Paul Smolenski
510(k) history	12 submissions · 12 cleared · 2015-2026