FDA 510(k) Premarket Notification

K232316 DEKA Infusion System, DEKA Administration Set

CLEARED

Mar 1, 2024
211 days to decision

K232316 · Product code: **LDR** · General Hospital
Source: https://www.510kdatabase.net/k232316/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Controller, Infusion, Intravascular, Electronic (LDR)
Date received	Aug 3, 2023
Decision date	Mar 1, 2024
Days to decision	211 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	11 submissions · 11 cleared · 2015-2025