FDA 510(k) Premarket Notification

K153760 Volumetric Infusion Controller

CLEARED

Oct 3, 2016
278 days to decision

K153760 · Product code: **LDR** · General Hospital
Source: https://www.510kdatabase.net/k153760/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Controller, Infusion, Intravascular, Electronic (LDR)
Date received	Dec 30, 2015
Decision date	Oct 3, 2016
Days to decision	278 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**DEKA Research & Development**
Location	Manchester, NH, US
Contact	Julie Perkins
510(k) history	3 submissions · 3 cleared · 2016-2020