FDA 510(k) Premarket Notification

K171954 ClearLine IV

CLEARED

Jan 25, 2018
210 days to decision

K171954 · Product code: **OKL** · General Hospital
Source: https://www.510kdatabase.net/k171954/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intravascular Administration Set, Automated Air Removal System (OKL)
Date received	Jun 29, 2017
Decision date	Jan 25, 2018
Days to decision	210 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Clearline MD**
Location	Woburn, MA, US
Contact	Rick Romeo
510(k) history	1 submissions · 1 cleared · 2018-2018