FDA 510(k) Premarket Notification

K162826 Encore Neutral

CLEARED

Jun 15, 2017
251 days to decision

K162826 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k162826/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Oct 7, 2016
Decision date	Jun 15, 2017
Days to decision	251 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Rymed Technologies, LLC**
Location	Austin, TX, US
Contact	Anna McCutchen
510(k) history	1 submissions · 1 cleared · 2017-2017