FDA 510(k) Premarket Notification

K160629 InPen

CLEARED

Jul 26, 2016
141 days to decision

K160629 · Product code: **FMF** · General Hospital
Source: https://www.510kdatabase.net/k160629/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Mar 7, 2016
Decision date	Jul 26, 2016
Days to decision	141 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Companion Medical, Inc.**
Location	San Diego, CA, US
Contact	JASPER BENKE
510(k) history	5 submissions · 5 cleared · 2016-2020