FDA 510(k) Premarket Notification

K160668 HumaPen Savvio

CLEARED

Jun 3, 2016
86 days to decision

K160668 · Product code: **FMF** · General Hospital
Source: https://www.510kdatabase.net/k160668/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Mar 9, 2016
Decision date	Jun 3, 2016
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Eli Lilly and Company, Inc.**
Location	Indianapolis, IN, US
Contact	Christine A. Phliips
510(k) history	2 submissions · 2 cleared · 2015-2016