FDA 510(k) Premarket Notification

K140568 CAREFINE PEN NEEDLE WITH QUINTAPOINT AND SUPERPOINT

CLEARED

May 13, 2014
69 days to decision

K140568 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k140568/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Mar 5, 2014
Decision date	May 13, 2014
Days to decision	69 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Facet Technologies, LLC**
Location	Kennesaw, GA, US
Contact	JENNIFER REGISTER
510(k) history	7 submissions · 7 cleared · 2014-2024