FDA 510(k) Premarket Notification

K133100 CAREFINE PEN NEEDLE

CLEARED

Jan 23, 2014
115 days to decision

K133100 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k133100/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Sep 30, 2013
Decision date	Jan 23, 2014
Days to decision	115 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Facet Technologies**
Location	Kennesaw, GA, US
Contact	MARY ANN KINARD
510(k) history	1 submissions · 1 cleared · 2014-2014