FDA 510(k) Premarket Notification

K160532 Greiner Holdex

CLEARED

Nov 3, 2016
251 days to decision

K160532 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k160532/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Feb 26, 2016
Decision date	Nov 3, 2016
Days to decision	251 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Greiner Bio-One Na, Inc.**
Location	Monroe, NC, US
Contact	MANFRED ABEL
510(k) history	5 submissions · 5 cleared · 2016-2019