FDA 510(k) Premarket Notification

K121476 INFILL GRAFT DELIVERY SYSTEM

CLEARED

Aug 29, 2012
103 days to decision

K121476 · Product code: **FMF** · General Hospital
Source: https://www.510kdatabase.net/k121476/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Syringe, Piston (FMF)
Date received	May 18, 2012
Decision date	Aug 29, 2012
Days to decision	103 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Pinnacle Spine Group, LLC**
Location	Dallas, TX, US
Contact	Rebecca K Pine
510(k) history	12 submissions · 12 cleared · 2011-2017