FDA 510(k) Premarket Notification

K102512 RMS SUBCUTANEOUS NEEDLE SET

CLEARED

May 20, 2011
261 days to decision

K102512 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k102512/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Sep 1, 2010
Decision date	May 20, 2011
Days to decision	261 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Repro-Med Systems, Inc.**
Location	Middletown, NY, US
Contact	ANDREW SEALFON
510(k) history	6 submissions · 5 cleared · 1985-2011