FDA 510(k) Premarket Notification

CLEARED

K120443 NEUTRAL LUER ACTIVATED DEVICE AND EXTENSION SETS WITH NEUTRAL LUER ACTIVATED DEVICE

May 22, 2012
98 days to decision

K120443 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k120443/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Feb 14, 2012
Decision date	May 22, 2012
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Baxter Healthcare Corporation - Renal Division**
Location	Mcgaw Park, IL, US
Contact	NANETTE HEDDEN
510(k) history	2 submissions · 2 cleared · 2010-2012