FDA 510(k) Premarket Notification

K123344 K-SHIELD ADVANTAGE PORT ACCESS INFUSION SET (PAIS)

CLEARED

Mar 7, 2013
127 days to decision

K123344 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k123344/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Oct 31, 2012
Decision date	Mar 7, 2013
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Kawasumi Laboratories, Inc.**
Location	Washington, DC, US
Contact	CHRISTINA HENZA
510(k) history	11 submissions · 11 cleared · 2002-2019