FDA 510(k) Premarket Notification

CLEARED

K190233 K-Shield Advantage Port Access Infusion Set (PAIS)

May 2, 2019
85 days to decision

K190233 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k190233/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Set, Administration, Intravascular (FPA)
Date received	Feb 6, 2019
Decision date	May 2, 2019
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Regulatory Compliance Associates, Inc.**
Contact	Valerie Followell

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov