

K100720 K-SHIELD PORT ACCESS INFUSION SET WITH HIGH PRESSURE TUBINGNov 18, 2010
248 days to decisionK100720 · Product code: **FPA** · General Hospital
Source: <https://www.510kdatabase.net/k100720/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Administration, Intravascular (FPA)
Date received	Mar 15, 2010
Decision date	Nov 18, 2010
Days to decision	248 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k100720/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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