

**K252355 K-SHIELD Advantage PORT ACCESS INFUSION SET
With High Pressure Tubing**Nov 26, 2025
120 days to decisionK252355 · Product code: PTI · General Hospital
Source: <https://www.510kdatabase.net/k252355/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Non-coring (huber) Needle (PTI)
Date received	Jul 29, 2025
Decision date	Nov 26, 2025
Days to decision	120 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sb-Kawasumi Laboratories, Inc.
Location	Kanagawa, JP
Contact	Kenichi Inamura
510(k) history	5 submissions · 5 cleared · 2022-2025

REGULATORY CONSULTANT

Consulting firm	Regulatory Compliance Associates, Inc. (Rca)
Contact	Valerie Followell

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252355/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026