FDA 510(k) Premarket Notification

K220799 K-SHIELD Zen

CLEARED

Aug 29, 2022
164 days to decision

K220799 · Product code: **JKA** · General Hospital
Source: https://www.510kdatabase.net/k220799/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubes, Vials, Systems, Serum Separators, Blood Collection (JKA)
Date received	Mar 18, 2022
Decision date	Aug 29, 2022
Days to decision	164 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Sb-Kawasumi Laboratories, Inc.**
Location	Kanagawa, JP
Contact	Shiro Agehama
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