FDA 510(k) Premarket Notification

K172957 Kawasumi Laboratories Blood Drawing Kit (BDK) System

CLEARED

Sep 28, 2018
367 days to decision

K172957 · Product code: **KSB** · General Hospital
Source: https://www.510kdatabase.net/k172957/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Set, Transfer (blood/plasma) (KSB)
Date received	Sep 26, 2017
Decision date	Sep 28, 2018
Days to decision	367 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Regulatory Compliance Associates, Inc.**
Contact	Lisa L. Michels

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