

**K172957 Kawasumi Laboratories Blood Drawing Kit (BDK)  
System**Sep 28, 2018  
367 days to decisionK172957 · 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	<b>Kawasumi Laboratories, Inc.</b>
Location	Washington, DC, US
Contact	Takayuki Nakajima
510(k) history	11 submissions · 11 cleared · 2002-2019

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Regulatory Compliance Associates, Inc.</b>
Contact	Lisa L. Michels

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k172957/>; 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 June 20, 2026