

K190485 Kawasumi Multiple Sample Adapter with Pre-Attached Holder (MBCH)Jul 8, 2019
131 days to decisionK190485 · Product code: **JKA** · General Hospital
Source: <https://www.510kdatabase.net/k190485/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubes, Vials, Systems, Serum Separators, Blood Collection (JKA)
Date received	Feb 27, 2019
Decision date	Jul 8, 2019
Days to decision	131 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Regulatory Compliance Associates, Inc. (Rca)
Contact	Lisa L. Michels

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/k190485/> 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