

**K001043 KAWASUMI LABORATORY BLOOD DRAWING KIT**May 19, 2000  
49 days to decisionK001043 · Product code: **KSB** · Hematology  
Source: <https://www.510kdatabase.net/k001043/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Set, Transfer (blood/plasma) (KSB) |
| Date received         | Mar 31, 2000                       |
| Decision date         | May 19, 2000                       |
| Days to decision      | 49 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|--|
| Company        | <b>Kawasumi Laboratories America, Inc.</b> |
| Location       | Tampa, FL, US                              |
| Contact        | JACK PAVLO                                 |
| 510(k) history | 6 submissions · 6 cleared · 2000-2010      |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k001043/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 20, 2026