

**K123344 K-SHIELD ADVANTAGE PORT ACCESS INFUSION SET (PAIS)**Mar 7, 2013  
127 days to decisionK123344 · Product code: **FPA** · General Hospital  
Source: <https://www.510kdatabase.net/k123344/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)       |
| Submission type       | Traditional                              |
| Device classification | Set, Administration, Intravascular (FPA) |
| Date received         | Oct 31, 2012                             |
| Decision date         | Mar 7, 2013                              |
| Days to decision      | 127 days                                 |
| Third-party review    | No                                       |
| Summary / Statement   | Summary                                  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Kawasumi Laboratories, Inc.</b>      |
| Location       | Washington, DC, US                      |
| Contact        | CHRISTINA HENZA                         |
| 510(k) history | 11 submissions · 11 cleared · 2002-2019 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k123344/>; 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