

K230408 K-SHIELD Zen (Model Numbers: PBMH/ PBMA/ PBM)Jun 1, 2023
106 days to decisionK230408 · Product code: **JKA** · General Hospital
Source: <https://www.510kdatabase.net/k230408/>**SUBMISSION DETAILS**

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|-----------------------|-----------------------------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Tubes, Vials, Systems, Serum Separators, Blood Collection (JKA) |
| Date received | Feb 15, 2023 |
| Decision date | Jun 1, 2023 |
| Days to decision | 106 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Sb-Kawasumi Laboratories, Inc. |
| Location | Kanagawa, JP |
| Contact | Shiro Agehama |
| 510(k) history | 5 submissions · 5 cleared · 2022-2025 |

REGULATORY CONSULTANT

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|-----------------|-----------------------------------------------------|
| Consulting firm | Regulatory Compliance Associates, Inc. (Rca) |
| Contact | Valerie Followell |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230408/> 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 May 26, 2026