

**K193514 AUTION MAX AX-4060 Urinalysis System**Apr 13, 2023  
1211 days to decisionK193514 · Product code: **JIL** · Chemistry  
Source: <https://www.510kdatabase.net/k193514/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                           |
| Submission type       | Traditional  |
| Device classification | Method, Enzymatic, Glucose (urinary, Non-quantitative) (JIL) |
| Date received         | Dec 19, 2019   |
| Decision date         | Apr 13, 2023   |
| Days to decision      | 1211 days  |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Arkray, Inc.</b>                     |
| Location       | Beverly, MA, US                         |
| Contact        | Hideko Kosaka                           |
| 510(k) history | 18 submissions · 18 cleared · 2002-2024 |

**REGULATORY CONSULTANT**

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|-----------------|---------------------------------|
| Consulting firm | <b>Arkray Factory USA, Inc.</b> |
| Contact         | Daya Ranamukhaarachchi          |

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.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k193514/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026