

K160062 AUTION ELEVEN Semi-Automated Urinalysis SystemOct 7, 2016
269 days to decisionK160062 · Product code: **JIL** · Chemistry
Source: <https://www.510kdatabase.net/k160062/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Method, Enzymatic, Glucose (urinary, Non-quantitative) (JIL)
Date received	Jan 12, 2016
Decision date	Oct 7, 2016
Days to decision	269 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Arkray, Inc.
Location	Beverly, MA, US
Contact	Tom Speikers (U.S. Agent)
510(k) history	18 submissions · 18 cleared · 2002-2024

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