

**K121456 AUTION HYBRID AU-4050 FULLY AUTOMATED
INTEGRATED URINE ANALYZER SYSTEM**Feb 1, 2013
261 days to decisionK121456 · Product code: **KQO** · Chemistry
Source: <https://www.510kdatabase.net/k121456/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Urinalysis System (KQO)
Date received	May 16, 2012
Decision date	Feb 1, 2013
Days to decision	261 days
Third-party review	No
Summary / Statement	Summary
Other names	URIFLET S 9HA URINE TEST STRIPS; AUTION CONTROL

APPLICANT

Company	Arkray, Inc.
Location	Beverly, MA, US
Contact	ADAM E TTL
510(k) history	18 submissions · 18 cleared · 2002-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k121456/> 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