

K232416 AUTION EYE AI-4510 Urine Particle Analysis SystemMay 3, 2024
266 days to decisionK232416 · Product code: **LKM** · Immunology
Source: <https://www.510kdatabase.net/k232416/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Counter, Urine Particle (LKM)
Date received	Aug 11, 2023
Decision date	May 3, 2024
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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