

K243144 X100/X100HT with Full Field Peripheral Blood Smear (PBS) Application

Jun 27, 2025
270 days to decision

K243144 · Product code: **JOY** · Hematology
Source: <https://www.510kdatabase.net/k243144/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Automated Cell-locating (JOY)
Date received	Sep 30, 2024
Decision date	Jun 27, 2025
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Scopio Labs , Ltd.
Location	Tel Aviv, IL
Contact	lfat Raved
510(k) history	4 submissions · 3 cleared · 2020-2025

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	Randy Prebula

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)
