

**K220013 X100HT with Slide Loader with Full Field Peripheral Blood Smear (PBS) Application**May 3, 2022  
119 days to decisionK220013 · Product code: **JOY** · Hematology  
Source: <https://www.510kdatabase.net/k220013/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Automated Cell-locating (JOY)
Date received	Jan 4, 2022
Decision date	May 3, 2022
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Scopio Labs , Ltd.</b>
Location	Tel Aviv, IL
Contact	Shahar Karny
510(k) history	4 submissions · 3 cleared · 2020-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Hogan Lovells US LLP</b>
Contact	Randy J. Prebula

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](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k220013/> 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 26, 2026