

K201301 X100 with Full Field Peripheral Blood Smear (PBS) Application

Oct 2, 2020
140 days to decisionK201301 · Product code: **JOY** · Hematology
Source: <https://www.510kdatabase.net/k201301/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Automated Cell-locating (JOY)
Date received	May 15, 2020
Decision date	Oct 2, 2020
Days to decision	140 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201301/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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