

K221309 AI100 with ShonitSep 19, 2023
502 days to decisionK221309 · Product code: **JOY** · Hematology
Source: <https://www.510kdatabase.net/k221309/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Automated Cell-locating (JOY)
Date received	May 5, 2022
Decision date	Sep 19, 2023
Days to decision	502 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sigtuple Technologies Pvt. , Ltd.
Location	Bangalore, IN
Contact	Tathagato Rai Dastidar
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Axteria Biomed Consulting, Inc.
Contact	Jinjie Hu

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

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