

**K040591 DUET SYSTEM**Sep 16, 2004  
192 days to decisionK040591 · Product code: **JOY** · Hematology  
Source: <https://www.510kdatabase.net/k040591/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Automated Cell-locating (JOY)
Date received	Mar 8, 2004
Decision date	Sep 16, 2004
Days to decision	192 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bioview , Ltd.</b>
Location	Ra&apos;Ananna, IL
Contact	DORIT WINITZ
510(k) history	5 submissions · 5 cleared · 2003-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k040591/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026