

**K200595 CellaVision DC-1, CellaVision DC-1 PPA**Oct 16, 2020  
224 days to decisionK200595 · Product code: **JOY** · Hematology  
Source: <https://www.510kdatabase.net/k200595/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Automated Cell-locating (JOY)
Date received	Mar 6, 2020
Decision date	Oct 16, 2020
Days to decision	224 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>CellaVision AB</b>
Location	Minneapolis,, MN, US
Contact	Magnus Johnsson
510(k) history	7 submissions · 7 cleared · 2001-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Axteria Biomed Consulting, Inc.</b>
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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200595/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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