

**K080595 CELLAVISION DM96 WITH THE BODY FLUID
APPLICATION**Dec 5, 2008
277 days to decisionK080595 · Product code: **JOY** · Hematology
Source: <https://www.510kdatabase.net/k080595/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Automated Cell-locating (JOY)
Date received	Mar 3, 2008
Decision date	Dec 5, 2008
Days to decision	277 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	CellaVision AB
Location	Minneapolis,, MN, US
Contact	CONSTANCE G BUNDY
510(k) history	7 submissions · 7 cleared · 2001-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k080595/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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