

**K171315 Advanced RBC Application**Aug 1, 2017  
89 days to decisionK171315 · Product code: **JOY** · Hematology  
Source: <https://www.510kdatabase.net/k171315/>**SUBMISSION DETAILS**

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|                       |                                       |
|-----------------------|---------------------------------------|
| Decision              | Substantially Equivalent (Cleared)    |
| Submission type       | Traditional                           |
| Device classification | Device, Automated Cell-locating (JOY) |
| Date received         | May 4, 2017                           |
| Decision date         | Aug 1, 2017                           |
| Days to decision      | 89 days                               |
| Third-party review    | No                                    |
| Summary / Statement   | Summary                               |

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k171315/> 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 June 18, 2026