

**K111204 CELL-DYN 22 PLUS CALIBRATOR**Dec 22, 2011  
237 days to decisionK111204 · Product code: **KRX** · Hematology  
Source: <https://www.510kdatabase.net/k111204/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator For Cell Indices (KRX)
Date received	Apr 29, 2011
Decision date	Dec 22, 2011
Days to decision	237 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Streck</b>
Location	La Vista, NE, US
Contact	Deborah Kipp
510(k) history	33 submissions · 33 cleared · 2005-2026

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111204/> 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 15, 2026