

K120745 XN CALOct 19, 2012
221 days to decisionK120745 · Product code: **KRX** · Hematology
Source: <https://www.510kdatabase.net/k120745/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator For Cell Indices (KRX)
Date received	Mar 12, 2012
Decision date	Oct 19, 2012
Days to decision	221 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Streck
Location	La Vista, NE, US
Contact	DEBORAH S KIPP
510(k) history	33 submissions · 33 cleared · 2005-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k120745/> Data sourced from FDA 510(k) public records (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. - Generated June 13, 2026