

K160585 XN CALDec 22, 2016
296 days to decisionK160585 · Product code: **KRX** · Hematology
Source: <https://www.510kdatabase.net/k160585/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator For Cell Indices (KRX)
Date received	Mar 1, 2016
Decision date	Dec 22, 2016
Days to decision	296 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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