FDA 510(k) Premarket Notification

K960557 CALIBRATION VERIFICATION ASSESSMENT (CVA)

CLEARED

Apr 3, 1996
54 days to decision

K960557 · Product code: **JPK** · Hematology
Source: https://www.510kdatabase.net/k960557/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mixture, Hematology Quality Control (JPK)
Date received	Feb 9, 1996
Decision date	Apr 3, 1996
Days to decision	54 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Streck Laboratories, Inc.**
Location	Mchenry, IL, US
Contact	THEODORE W HEISE
510(k) history	70 submissions · 70 cleared · 1977-2004