FDA 510(k) Premarket Notification

K090201 UA-CELLULAR FOR IQ

CLEARED

Mar 27, 2009
59 days to decision

K090201 · Product code: **JPK** · Hematology
Source: https://www.510kdatabase.net/k090201/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mixture, Hematology Quality Control (JPK)
Date received	Jan 27, 2009
Decision date	Mar 27, 2009
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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