FDA 510(k) Premarket Notification

CLEARED

K100684 CELLTRACKS AUTOPREP SYSTEM MODEL:9541

Aug 26, 2010
169 days to decision

K100684 · Product code: **GKH** · Hematology
Source: https://www.510kdatabase.net/k100684/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Apparatus, Automated Blood Cell Diluting (GKH)
Date received	Mar 10, 2010
Decision date	Aug 26, 2010
Days to decision	169 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Veridex, LLC**
Location	Raritan, NJ, US
Contact	SARAH MCMANUS
510(k) history	12 submissions · 12 cleared · 2004-2013

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k100684/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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