

K121752 AVIE TOTAL HB TEST SYSTEMJan 7, 2013
207 days to decisionK121752 · Product code: **GKR** · Hematology
Source: <https://www.510kdatabase.net/k121752/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Hemoglobin, Automated (GKR)
Date received	Jun 14, 2012
Decision date	Jan 7, 2013
Days to decision	207 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Mec Dynamics Corp
Location	Santa Clara, CA, US
Contact	EMMANUAL MPOCK
510(k) history	4 submissions · 4 cleared · 2009-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k121752/> 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 9, 2026