

**K090093 STANBIO LABORATORY HEMOPOINT H2 DM
HEMOGLOBIN MEASUREMENT SYSTEM**

Jun 10, 2009
147 days to decision

K090093 · Product code: **GKR** · Hematology
Source: <https://www.510kdatabase.net/k090093/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Hemoglobin, Automated (GKR)
Date received	Jan 14, 2009
Decision date	Jun 10, 2009
Days to decision	147 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Stanbio Laboratory
Location	Mchenry, IL, US
Contact	KIRK JOHNSON
510(k) history	47 submissions · 47 cleared · 1977-2009

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k090093/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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