

**K081719 STANBIO LABORATORY HEMOPOINT H2
HEMOGLOBIN MEASUREMENT SYSTEM**

Jul 18, 2008
30 days to decision

K081719 · Product code: **GKR** · Hematology
Source: <https://www.510kdatabase.net/k081719/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Hemoglobin, Automated (GKR)
Date received	Jun 18, 2008
Decision date	Jul 18, 2008
Days to decision	30 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/k081719/>; 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 23, 2026