

K122553 MISSION PLUS HB HEMOGLOBIN TESTING SYSTEMAug 5, 2013
349 days to decisionK122553 · Product code: **GKR** · Hematology
Source: <https://www.510kdatabase.net/k122553/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Hemoglobin, Automated (GKR)
Date received	Aug 21, 2012
Decision date	Aug 5, 2013
Days to decision	349 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	ACON Laboratories, Inc.
Location	San Diego, CA, US
Contact	QIYI XIE
Website	http://www.aconlabs.com/
510(k) history	85 submissions · 85 cleared · 1998-2025

ACON Laboratories, Inc. is a global medical device manufacturer headquartered in San Diego, California. The company develops and manufactures diagnostic and point-of-care testing devices for hospitals, clinical laboratories, physician offices, blood banks, pharmacies, and veterinary clinics. ACON operates in over 130 countries and maintains FDA-registered manufacturing facilities with ISO 13485 certification. ACON has received FDA 510(k) clearances from total submissions since 1998, with no denied submissions. The company specializes in chemistry devices, including blood ...
