

K122599 ADVIA CHEMISTRY MYOGLOBIN REAGENT, ADVIA CHEMISTRY MYOGLBIN CALIBRATOROct 3, 2012
37 days to decisionK122599 · Product code: **DDR** · Chemistry
Source: <https://www.510kdatabase.net/k122599/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Myoglobin, Antigen, Antiserum, Control (DDR)
Date received	Aug 27, 2012
Decision date	Oct 3, 2012
Days to decision	37 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthcare Diagnostics, Inc.
Location	New York, NY, US
Contact	KIRA GORDON
Website	https://www.siemens-healthineers.com
510(k) history	152 submissions · 151 cleared · 2008-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k122599/> 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 May 28, 2026