

K020710 BIOTEST HEMOGLOBIN MEASURING SYSTEMAug 14, 2002
162 days to decisionK020710 · Product code: **GKR** · Hematology
Source: <https://www.510kdatabase.net/k020710/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, Hemoglobin, Automated (GKR)
Date received	Mar 5, 2002
Decision date	Aug 14, 2002
Days to decision	162 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Biotest Medizintechnik GmbH
Location	Richmond, VA, US
Contact	MARK LICATA
510(k) history	1 submissions · 1 cleared · 2002-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k020710/> 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 28, 2026