

**K963106 CHROMOLIZE PAI-1 KIT**Nov 18, 1996  
98 days to decisionK963106 · Product code: **GGP** · Hematology  
Source: <https://www.510kdatabase.net/k963106/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Qualitative And Quantitative Factor Deficiency (GGP)
Date received	Aug 12, 1996
Decision date	Nov 18, 1996
Days to decision	98 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Medical Diagnostic Technologies, Inc.</b>
Location	Augusta, GA, US
Contact	MICHAEL D BICK, PH.D.
510(k) history	57 submissions · 57 cleared · 1985-2006

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k963106/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 18, 2026