FDA 510(k) Premarket Notification

K963106 CHROMOLIZE PAI-1 KIT

CLEARED

Nov 18, 1996
98 days to decision

K963106 · 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	**Medical Diagnostic Technologies, Inc.**
Location	Augusta, GA, US
Contact	MICHAEL D BICK, PH.D.
510(k) history	57 submissions · 57 cleared · 1985-2006