FDA 510(k) Premarket Notification

K022331 ADVIA 120 HEMATOLOGY SYSTEM, CEREBROSPINAL FLUID METHOD

CLEARED

Sep 11, 2002
55 days to decision

K022331 · Product code: **GKL** · Hematology
Source: https://www.510kdatabase.net/k022331/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Counter, Cell, Automated (particle Counter) (GKL)
Date received	Jul 18, 2002
Decision date	Sep 11, 2002
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bayer Diagnostics Corp.**
Location	Medfield, MA, US
Contact	KENNETH T EDDS
510(k) history	32 submissions · 32 cleared · 2000-2003