FDA 510(k) Premarket Notification

K042251 BAYER ADVIA 2120 HEMATOLOGY ANALYZER WITH AUTOSLIDE SYSTEM

CLEARED

Sep 17, 2004
28 days to decision

K042251 · Product code: **GKZ** · Hematology
Source: https://www.510kdatabase.net/k042251/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Counter, Differential Cell (GKZ)
Date received	Aug 20, 2004
Decision date	Sep 17, 2004
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bayer Healthcare, LLC**
Location	New York, NY, US
Contact	ANDRES HOLLE
510(k) history	46 submissions · 46 cleared · 2003-2018