FDA 510(k) Premarket Notification

K012357 CA 15-3 ASSAY FOR THE ADVIA CENTAUR SYSTEM

CLEARED

Feb 28, 2002
218 days to decision

K012357 · Product code: **MOI** · Immunology
Source: https://www.510kdatabase.net/k012357/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Immunological, Antigen, Tumor (MOI)
Date received	Jul 25, 2001
Decision date	Feb 28, 2002
Days to decision	218 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