FDA 510(k) Premarket Notification

K041133 MODIFICATION TO BAYER ADVIA CENTAUR AUTOMATED CHEMILUMINESCENCE ANALYZER

CLEARED

Jul 2, 2004
63 days to decision

K041133 · Product code: **CDD** · Chemistry
Source: https://www.510kdatabase.net/k041133/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Radioassay, Vitamin B12 (CDD)
Date received	Apr 30, 2004
Decision date	Jul 2, 2004
Days to decision	63 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