

K042808 ADVIA IMS CARBAMAZEPINE METHODFeb 8, 2005
119 days to decisionK042808 · Product code: **KLT** · Chemistry
Source: <https://www.510kdatabase.net/k042808/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Carbamazepine (KLT)
Date received	Oct 12, 2004
Decision date	Feb 8, 2005
Days to decision	119 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

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