

**K061139 BAYER ADVIA IMS PSA CALIBRATOR AND ADVIA IMS
CPSA CALIBRATORS**Jul 6, 2006
73 days to decisionK061139 · Product code: JIT · Immunology
Source: <https://www.510kdatabase.net/k061139/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Calibrator, Secondary (JIT)
Date received	Apr 24, 2006
Decision date	Jul 6, 2006
Days to decision	73 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k061139/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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