

K033791 BAYER SPECIFIC PROTEIN REFERENCE SERUMFeb 13, 2004
71 days to decisionK033791 · Product code: **JIX** · Chemistry
Source: <https://www.510kdatabase.net/k033791/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Calibrator, Multi-analyte Mixture (JIX)
Date received	Dec 4, 2003
Decision date	Feb 13, 2004
Days to decision	71 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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