

K052503 TROPONIN I ULTRA ASSAY AND CALIBRATOR FOR THE ADVIA IMS SYSTEM

Dec 14, 2005
92 days to decision

K052503 · Product code: **MMI** · Chemistry
Source: <https://www.510kdatabase.net/k052503/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay Method, Troponin Subunit (MMI)
Date received	Sep 13, 2005
Decision date	Dec 14, 2005
Days to decision	92 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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Device record: <https://www.510kdatabase.net/k052503/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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