

K053020 TNL-ULTRA ASSAY FOR THE ADVIA CENTAUR SYSTEMDec 30, 2005
65 days to decisionK053020 · Product code: **MMI** · Chemistry
Source: <https://www.510kdatabase.net/k053020/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay Method, Troponin Subunit (MMI)
Date received	Oct 26, 2005
Decision date	Dec 30, 2005
Days to decision	65 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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