

**K063243 VIDAS TROPONIN I ULTRA (TNIU) ASSAY, MODEL 30
448**Dec 14, 2007
414 days to decisionK063243 · Product code: **MMI** · Chemistry
Source: <https://www.510kdatabase.net/k063243/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay Method, Troponin Subunit (MMI)
Date received	Oct 26, 2006
Decision date	Dec 14, 2007
Days to decision	414 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	bioMerieux, Inc.
Location	Mchenry, IL, US
Contact	NIKITA S MAPP
510(k) history	251 submissions · 250 cleared · 1983-2026

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