

K230994 Alinity i STAT High Sensitivity Troponin-IMay 4, 2023
27 days to decisionK230994 · Product code: **MMI** · Chemistry
Source: <https://www.510kdatabase.net/k230994/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Immunoassay Method, Troponin Subunit (MMI)
Date received	Apr 7, 2023
Decision date	May 4, 2023
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Abbott Laboratories Diagnostics Division
Location	Abbott Park, IL, US
Contact	Judi Wallach
510(k) history	4 submissions · 4 cleared · 2019-2024

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