

K241165 Atellica® IM High-Sensitivity Troponin I (TnIH)Jul 25, 2024
90 days to decisionK241165 · Product code: **MMI** · Chemistry
Source: <https://www.510kdatabase.net/k241165/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay Method, Troponin Subunit (MMI)
Date received	Apr 26, 2024
Decision date	Jul 25, 2024
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthcare Diagnostics, Inc.
Location	New York, NY, US
Contact	Amy Tyler
Website	https://www.siemens-healthineers.com
510(k) history	152 submissions · 151 cleared · 2008-2026

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