

K051925 CARESTART CARDIAC 3-IN-1 TROPONIN 1/CK-MB/MYOGLOBIN

Nov 29, 2005
134 days to decision

K051925 · Product code: **MMI** · Chemistry
Source: <https://www.510kdatabase.net/k051925/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay Method, Troponin Subunit (MMI)
Date received	Jul 18, 2005
Decision date	Nov 29, 2005
Days to decision	134 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Access Bio Incorporate
Location	North Brunswick, NJ, US
Contact	YOUNG HO CHOI
510(k) history	4 submissions · 4 cleared · 2003-2005

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k051925/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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