

K882795 DADE(R) CK-MB IMMUNOASSAY CONTROLAug 29, 1988
54 days to decisionK882795 · Product code: **JJT** · Chemistry
Source: <https://www.510kdatabase.net/k882795/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Controls (assayed And Unassayed) (JJT)
Date received	Jul 6, 1988
Decision date	Aug 29, 1988
Days to decision	54 days
Third-party review	No

APPLICANT

Company	Baxter Healthcare Corp
Location	Mchenry, IL, US
Contact	JEANNE-MARIE VARGA
510(k) history	505 submissions · 496 cleared · 1977-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k882795/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 17, 2026