

K962549 VIDAS CREATINE KINASE MB ASSAY 30-421Aug 30, 1996
63 days to decisionK962549 · Product code: **JHX** · Chemistry
Source: <https://www.510kdatabase.net/k962549/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorometric Method, Cpk Or Isoenzymes (JHX)
Date received	Jun 28, 1996
Decision date	Aug 30, 1996
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biomerieux Vitek, Inc.
Location	Hazelwood, MO, US
Contact	TERRY MCGOVERN
510(k) history	49 submissions · 49 cleared · 1992-1998

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