

K832139 TANDEM - E-CKMB IMMUNOENZYMETRIC ASSAYAug 12, 1983
46 days to decisionK832139 · Product code: **JHY** · Chemistry
Source: <https://www.510kdatabase.net/k832139/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colorimetric Method, Cpk Or Isoenzymes (JHY)
Date received	Jun 27, 1983
Decision date	Aug 12, 1983
Days to decision	46 days
Third-party review	No

APPLICANT

Company	Hybritech, Inc.
Location	Mchenry, IL, US
510(k) history	63 submissions · 63 cleared · 1981-1997

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Device record: <https://www.510kdatabase.net/k832139/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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