

K823507 TANDEM-E -IGE IMMUNOEZYMETRIC ASSAYDec 28, 1982
34 days to decisionK823507 · Product code: **DGC** · Chemistry
Source: <https://www.510kdatabase.net/k823507/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ige, Antigen, Antiserum, Control (DGC)
Date received	Nov 24, 1982
Decision date	Dec 28, 1982
Days to decision	34 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/k823507/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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