

K833194 TANDEM R-TOTAL B-GCG KITJan 18, 1984
121 days to decisionK833194 · Product code: **JHI** · Chemistry
Source: <https://www.510kdatabase.net/k833194/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Sep 19, 1983
Decision date	Jan 18, 1984
Days to decision	121 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/k833194/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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