

K842633 TANDEM FAST VISUAL HCG ASSAY KIT -Aug 23, 1984
45 days to decisionK842633 · Product code: **JHI** · Chemistry
Source: <https://www.510kdatabase.net/k842633/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Jul 9, 1984
Decision date	Aug 23, 1984
Days to decision	45 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/k842633/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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