

**K865057 TANDEM R ICONR II HCG(SERUM)
IMMUNOENZYMETRIC ASSAY**Mar 10, 1987
76 days to decisionK865057 · Product code: JHI · Chemistry
Source: <https://www.510kdatabase.net/k865057/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Dec 24, 1986
Decision date	Mar 10, 1987
Days to decision	76 days
Third-party review	No

APPLICANT

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

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