

**K871235 TANDEM(R) ICON(R) QSR(TM) HCG IMMUNO. ASSAY
KIT**Jun 3, 1987
68 days to decisionK871235 · Product code: JHI · Chemistry
Source: <https://www.510kdatabase.net/k871235/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Mar 27, 1987
Decision date	Jun 3, 1987
Days to decision	68 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k871235/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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