

K821944 TANDEM HCG IMMUNOEZYMETRIC ASSAY KITJul 22, 1982
23 days to decisionK821944 · Product code: **JHI** · Chemistry
Source: <https://www.510kdatabase.net/k821944/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Visual, Pregnancy Hcg, Prescription Use (JHI) |
| Date received | Jun 29, 1982 |
| Decision date | Jul 22, 1982 |
| Days to decision | 23 days |
| Third-party review | No |

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k821944/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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