

K820822 TANDEM HCG KITApr 29, 1982
36 days to decisionK820822 · Product code: **JHI** · Chemistry
Source: <https://www.510kdatabase.net/k820822/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Visual, Pregnancy Hcg, Prescription Use (JHI) |
| Date received | Mar 24, 1982 |
| Decision date | Apr 29, 1982 |
| Days to decision | 36 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/k820822/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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