

K843407 ENCORE HCG REAGENTOct 4, 1984
34 days to decisionK843407 · Product code: **JHI** · Chemistry
Source: <https://www.510kdatabase.net/k843407/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Aug 31, 1984
Decision date	Oct 4, 1984
Days to decision	34 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/k843407/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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