

K821366 TANDEM - HGH KITJun 10, 1982
31 days to decisionK821366 · Product code: **CFL** · Chemistry
Source: <https://www.510kdatabase.net/k821366/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Human Growth Hormone (CFL)
Date received	May 10, 1982
Decision date	Jun 10, 1982
Days to decision	31 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/k821366/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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