FDA 510(k) Premarket Notification

K820822 TANDEM HCG KIT

CLEARED

Apr 29, 1982
36 days to decision

K820822 · 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