FDA 510(k) Premarket Notification

K812461 TANDEM QUALITATIVE HCG KIT

CLEARED

Oct 13, 1981
43 days to decision

K812461 · Product code: **JHI** · Chemistry
Source: https://www.510kdatabase.net/k812461/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Aug 31, 1981
Decision date	Oct 13, 1981
Days to decision	43 days
Third-party review	No

APPLICANT

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