FDA 510(k) Premarket Notification

K821366 TANDEM - HGH KIT

CLEARED

Jun 10, 1982
31 days to decision

K821366 · 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