FDA 510(k) Premarket Notification

K802913 TAN DEM* - IGE KIT

CLEARED

May 29, 1981
192 days to decision

K802913 · Product code: **DGC** · Chemistry
Source: https://www.510kdatabase.net/k802913/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ige, Antigen, Antiserum, Control (DGC)
Date received	Nov 18, 1980
Decision date	May 29, 1981
Days to decision	192 days
Third-party review	No

APPLICANT

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