FDA 510(k) Premarket Notification

K833275 GMP CIQ ELISA TEST KIT

CLEARED

Jun 22, 1984
275 days to decision

K833275 · Product code: **DAK** · Immunology
Source: https://www.510kdatabase.net/k833275/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Complement C1q, Antigen, Antiserum, Control (DAK)
Date received	Sep 21, 1983
Decision date	Jun 22, 1984
Days to decision	275 days
Third-party review	No

APPLICANT

Company	**Gamma Medical Products, Inc.**
Location	Mchenry, IL, US
510(k) history	2 submissions · 2 cleared · 1982-1984