FDA 510(k) Premarket Notification

K822661 RAPID REAGIN CARD TEST

CLEARED

Sep 21, 1982
18 days to decision

K822661 · Product code: **GMQ** · Microbiology
Source: https://www.510kdatabase.net/k822661/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigens, Nontreponemal, All (GMQ)
Date received	Sep 3, 1982
Decision date	Sep 21, 1982
Days to decision	18 days
Third-party review	No

APPLICANT

Company	**Oxoid U.S.A., Inc.**
Location	Mchenry, IL, US
510(k) history	93 submissions · 93 cleared · 1980-1989