FDA 510(k) Premarket Notification

K820567 TREP CARD EIKEN

CLEARED

Apr 14, 1982
43 days to decision

K820567 · Product code: **GMQ** · Microbiology
Source: https://www.510kdatabase.net/k820567/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigens, Nontreponemal, All (GMQ)
Date received	Mar 2, 1982
Decision date	Apr 14, 1982
Days to decision	43 days
Third-party review	No

APPLICANT

Company	**Syn-Kit, Inc.**
Location	Walker, MI, US
510(k) history	34 submissions · 34 cleared · 1980-1986