FDA 510(k) Premarket Notification

K955136 RPR CARD TEST KIT

CLEARED

Jul 29, 1996
259 days to decision

K955136 · Product code: **GMQ** · Microbiology
Source: https://www.510kdatabase.net/k955136/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigens, Nontreponemal, All (GMQ)
Date received	Nov 13, 1995
Decision date	Jul 29, 1996
Days to decision	259 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Remel, L.P.**
Location	Lenexa, KS, US
Contact	DAVID A WALL
510(k) history	10 submissions · 10 cleared · 1996-1997

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k955136/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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