FDA 510(k) Premarket Notification

K896433 MODIFIED RUBAGEN

CLEARED

Nov 29, 1989
20 days to decision

K896433 · Product code: **LQN** · Microbiology
Source: https://www.510kdatabase.net/k896433/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Agglutination Assay, Rubella (LQN)
Date received	Nov 9, 1989
Decision date	Nov 29, 1989
Days to decision	20 days
Third-party review	No

APPLICANT

Company	**Biokit USA, Inc.**
Location	Mchenry, IL, US
Contact	IGNACIO ODRIOZOLA
510(k) history	16 submissions · 16 cleared · 1984-1993