FDA 510(k) Premarket Notification

K920378 PACE 2 SYSTEM FOR CHLAMYDIA TRACHOMATIS

CLEARED

Apr 29, 1992
91 days to decision

K920378 · Product code: **LSK** · Microbiology
Source: https://www.510kdatabase.net/k920378/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dna-reagents, Chlamydia (LSK)
Date received	Jan 29, 1992
Decision date	Apr 29, 1992
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Gen-Probe, Inc.**
Location	San Diego, CA, US
Contact	RUBEN CHAIREZ
Website	http://www.gen-probe.com
510(k) history	62 submissions · 62 cleared · 1985-2013