FDA 510(k) Premarket Notification

K871795 RAPID DIAGNOSTIC SYSTEM FOR MYCOBACTERIUM TUBER.

CLEARED

Jul 30, 1987
84 days to decision

K871795 · Product code: **LQF** · Microbiology
Source: https://www.510kdatabase.net/k871795/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dna-reagents, Mycobacterium Spp. (LQF)
Date received	May 7, 1987
Decision date	Jul 30, 1987
Days to decision	84 days
Third-party review	No

APPLICANT

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