FDA 510(k) Premarket Notification

K851271 LEGIONELLA CULTURE CONFIRMATIN KIT

CLEARED

Jul 8, 1985
98 days to decision

K851271 · Product code: **GRO** · Microbiology
Source: https://www.510kdatabase.net/k851271/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, Fluorescent, All Types, Hemophilus Spp. (GRO)
Date received	Apr 1, 1985
Decision date	Jul 8, 1985
Days to decision	98 days
Third-party review	No

APPLICANT

Company	**Gen-Probe, Inc.**
Location	San Diego, CA, US
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510(k) history	62 submissions · 62 cleared · 1985-2013