FDA 510(k) Premarket Notification

K934330 TRANSGROW

CLEARED

Dec 17, 1993
105 days to decision

K934330 · Product code: **JTY** · Microbiology
Source: https://www.510kdatabase.net/k934330/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Culture Media, For Isolation Of Pathogenic Neisseria (JTY)
Date received	Sep 3, 1993
Decision date	Dec 17, 1993
Days to decision	105 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Hardy Diagnostics**
Location	Santa Maria, CA, US
Contact	MELISSA M TRAYLOR
510(k) history	109 submissions · 109 cleared · 1993-2026

Hardy Diagnostics is an American health care company headquartered in Santa Maria, California. The company manufactures bacteriological culture media, reagents, automated microscope slide staining machines, and rapid identification kits for microbiological testing. Hardy Diagnostics has received FDA 510(k) clearances from total submissions since 1993. The company specializes exclusively in Microbiology devices, with its most recent clearance in 2025. Recent cleared devices include antibiotic susceptibility testing disks and viral transport media. The company manufactures ...