FDA 510(k) Premarket Notification

K902571 MODIFICATION OF SEROCARD RUBELLA IGG TEST

CLEARED

Sep 5, 1990
90 days to decision

K902571 · Product code: **LFX** · Microbiology
Source: https://www.510kdatabase.net/k902571/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rubella (LFX)
Date received	Jun 7, 1990
Decision date	Sep 5, 1990
Days to decision	90 days
Third-party review	No

APPLICANT

Company	**Disease Detection International, Inc.**
Location	Irvine, CA, US
Contact	JULIE WHITESIDE
510(k) history	20 submissions · 20 cleared · 1988-1994