FDA 510(k) Premarket Notification

K884247 MODIFIED DDI SEROCARD RUBELLA IGG TEST KIT

CLEARED

Apr 10, 1989
181 days to decision

K884247 · Product code: **LFX** · Microbiology
Source: https://www.510kdatabase.net/k884247/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rubella (LFX)
Date received	Oct 11, 1988
Decision date	Apr 10, 1989
Days to decision	181 days
Third-party review	No

APPLICANT

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