FDA 510(k) Premarket Notification

K873780 MODIFICATION RUBELLA IGM EIA TEST KIT

CLEARED

Oct 15, 1987
35 days to decision

K873780 · Product code: **LFX** · Microbiology
Source: https://www.510kdatabase.net/k873780/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rubella (LFX)
Date received	Sep 10, 1987
Decision date	Oct 15, 1987
Days to decision	35 days
Third-party review	No

APPLICANT

Company	**Labsystems, Inc.**
Location	Walker, MI, US
Contact	NANCY SKOWRONSKI
510(k) history	17 submissions · 17 cleared · 1984-1993

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k873780/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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