

K925355 BIOSIGN(TM_ RUBELLA - RUBELLA ANTIBODY TESTJul 12, 1994
628 days to decisionK925355 · Product code: LFX · Microbiology
Source: <https://www.510kdatabase.net/k925355/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rubella (LFX)
Date received	Oct 22, 1992
Decision date	Jul 12, 1994
Days to decision	628 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Princeton Biomedix
Location	Mchenry, IL, US
Contact	JEMO KANG
510(k) history	14 submissions · 14 cleared · 1976-1995

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