

K911393 RUBENOSTIKA IGG MICROELISA SYSTEMApr 29, 1991
31 days to decisionK911393 · Product code: LFX · Microbiology
Source: <https://www.510kdatabase.net/k911393/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rubella (LFX)
Date received	Mar 29, 1991
Decision date	Apr 29, 1991
Days to decision	31 days
Third-party review	No

APPLICANT

Company	Organon Teknika Corp.
Location	Mchenry, IL, US
Contact	ANN M QUINN
510(k) history	130 submissions · 129 cleared · 1980-2000

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