

K853069 TANDEM ICON RUBELLA IGG IMMUNOENZYMETRIC ASSAY KITJan 1, 1986
163 days to decisionK853069 · Product code: LFX · Microbiology
Source: <https://www.510kdatabase.net/k853069/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rubella (LFX)
Date received	Jul 22, 1985
Decision date	Jan 1, 1986
Days to decision	163 days
Third-party review	No

APPLICANT

Company	Hybritech, Inc.
Location	Mchenry, IL, US
Contact	JOHN F BRUNI
510(k) history	63 submissions · 63 cleared · 1981-1997

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Device record: <https://www.510kdatabase.net/k853069/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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