

K942619 EMIT 2000 DIGOXIN ASSAY/CALIBRATORSSep 20, 1994
117 days to decisionK942619 · Product code: **LFM** · Chemistry
Source: <https://www.510kdatabase.net/k942619/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Digitoxin (LFM)
Date received	May 26, 1994
Decision date	Sep 20, 1994
Days to decision	117 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Syva Co.
Location	Mchenry, IL, US
Contact	PAUL J ROGERS JR.
510(k) history	448 submissions · 447 cleared · 1976-2001

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