

K915465 DIGITOXIN FPIA REAGENT SETJan 27, 1992
56 days to decisionK915465 · Product code: **LFM** · Toxicology
Source: <https://www.510kdatabase.net/k915465/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Digitoxin (LFM)
Date received	Dec 2, 1991
Decision date	Jan 27, 1992
Days to decision	56 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Sigma Diagnostics, Inc.
Location	Mchenry, IL, US
Contact	BARRY D ROBINS
510(k) history	164 submissions · 164 cleared · 1984-2002

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