

K970546 ACS DIGITOXINJul 14, 1997
152 days to decisionK970546 · Product code: **LFM** · Chemistry
Source: <https://www.510kdatabase.net/k970546/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Digitoxin (LFM)
Date received	Feb 12, 1997
Decision date	Jul 14, 1997
Days to decision	152 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Chiron Diagnostics Corp.
Location	Medfield, MA, US
Contact	THOMAS F FLYNN
510(k) history	20 submissions · 20 cleared · 1997-1999

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