

**K020758 VARELISA CARDIOLIPIN IGM ANTIBODIES, MODELS
15648 & 15696**May 2, 2002
56 days to decisionK020758 · Product code: **MID** · Immunology
Source: <https://www.510kdatabase.net/k020758/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Anticardiolipin Immunological (MID)
Date received	Mar 7, 2002
Decision date	May 2, 2002
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Pharmacia Deutschland GmbH
Location	Freiburg, DE
Contact	MICHARL LINSS
510(k) history	10 submissions · 10 cleared · 2002-2004

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