

K041043 VARELISA PR3 ANCA, MODEL NUMBER 17748/17796Jul 2, 2004
71 days to decisionK041043 · Product code: **MOB** · Immunology
Source: <https://www.510kdatabase.net/k041043/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB)
Date received	Apr 22, 2004
Decision date	Jul 2, 2004
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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