

K041040 VARELISA MPO ANCA, MODEL 17648/17696Jun 16, 2004
55 days to decisionK041040 · Product code: **MOB** · Immunology
Source: <https://www.510kdatabase.net/k041040/>**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	Jun 16, 2004
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sweden Diagnostics (Germany) GmbH
Location	Freiburg, DE
Contact	MICHAEL LINSS
510(k) history	8 submissions · 8 cleared · 2004-2005

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