

K050625 VARELISA RECOMBI ANA PROFILE, MODEL 18496Apr 26, 2005
46 days to decisionK050625 · Product code: **LJM** · Immunology
Source: <https://www.510kdatabase.net/k050625/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Mar 11, 2005
Decision date	Apr 26, 2005
Days to decision	46 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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