

K050967 VARELISA RECOMBI CTD SCREEN, MODEL 13096Jun 28, 2005
71 days to decisionK050967 · Product code: **LJM** · Immunology
Source: <https://www.510kdatabase.net/k050967/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Apr 18, 2005
Decision date	Jun 28, 2005
Days to decision	71 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k050967/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026