

**K932876 DIASTAT ANTI-NUCLEAR ANTIBODY (ANA) KIT**Nov 15, 1993  
154 days to decisionK932876 · Product code: **LKJ** · Immunology  
Source: <https://www.510kdatabase.net/k932876/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Antigen, Control (LKJ)
Date received	Jun 14, 1993
Decision date	Nov 15, 1993
Days to decision	154 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Shield Diagnostics, Ltd.</b>
Location	Scotland, KN
Contact	GEORGE ZAJICEK
510(k) history	27 submissions · 27 cleared · 1990-2000

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k932876/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 28, 2026