

**K932877 DIASTAT ANTI-CENTROMERE KIT**Oct 15, 1993  
123 days to decisionK932877 · Product code: LLL · Immunology  
Source: <https://www.510kdatabase.net/k932877/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Jun 14, 1993
Decision date	Oct 15, 1993
Days to decision	123 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k932877/> 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