

**K905192 DIASTAT ANTI-SM/RNP**Dec 7, 1990  
18 days to decisionK905192 · Product code: **LKP** · Immunology  
Source: <https://www.510kdatabase.net/k905192/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti-sm Antibody, Antigen And Control (LKP)
Date received	Nov 19, 1990
Decision date	Dec 7, 1990
Days to decision	18 days
Third-party review	No

**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/k905192/>; 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