

K905190 DIASTAT ENA PROFILEDec 7, 1990
18 days to decisionK905190 · Product code: **LJM** · Immunology
Source: <https://www.510kdatabase.net/k905190/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Nov 19, 1990
Decision date	Dec 7, 1990
Days to decision	18 days
Third-party review	No

APPLICANT

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

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