

K944505 DIASTAT ENA SINGLE WELL SCREEN KITNov 21, 1994
68 days to decisionK944505 · Product code: LLL · Immunology
Source: <https://www.510kdatabase.net/k944505/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Sep 14, 1994
Decision date	Nov 21, 1994
Days to decision	68 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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