

K912292 DIASTAT ANTI-JO-1 KITJul 30, 1991
68 days to decisionK912292 · Product code: **DHN** · Immunology
Source: <https://www.510kdatabase.net/k912292/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Indirect Immunofluorescent, Antigen, Control (DHN)
Date received	May 23, 1991
Decision date	Jul 30, 1991
Days to decision	68 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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