

K912291 DISTAT ANTI-SCL-70 KITJul 30, 1991
68 days to decisionK912291 · Product code: **LKJ** · Immunology
Source: <https://www.510kdatabase.net/k912291/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Antigen, Control (LKJ)
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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