

K921265 DIASTAT ANTI-CARDIOLIPIN KITAug 3, 1992
140 days to decisionK921265 · Product code: **MID** · Immunology
Source: <https://www.510kdatabase.net/k921265/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Anticardiolipin Immunological (MID)
Date received	Mar 16, 1992
Decision date	Aug 3, 1992
Days to decision	140 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k921265/> Data sourced from FDA 510(k) public records (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. - Generated June 28, 2026