

**K001574 DIASTAT ANTI-CARDIOLIPIN IGG/IGM, MODEL FCAR
600**Jun 9, 2000
18 days to decisionK001574 · Product code: **MID** · Immunology
Source: <https://www.510kdatabase.net/k001574/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Anticardiolipin Immunological (MID)
Date received	May 22, 2000
Decision date	Jun 9, 2000
Days to decision	18 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Axis-Shield
Location	Dundee Tayside, Scotland, GB
Contact	EILEEN A MCCAFFERTY
510(k) history	1 submissions · 1 cleared · 2000-2000

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k001574/>; 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 29, 2026