

**K020348 ABBOTT AXSYM ANTI-THYROID-PEROXIDASE,
MODELS5F57 COMPRISING STANDARDS/CALIBRATORS**May 2, 2002
87 days to decisionK020348 · Product code: **JZO** · Immunology
Source: <https://www.510kdatabase.net/k020348/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Thyroid Autoantibody (JZO)
Date received	Feb 4, 2002
Decision date	May 2, 2002
Days to decision	87 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Axis-Shield Diagnostics, Ltd.
Location	Dundee, GB
Contact	EILEEN A MCCAFFERTY
Website	http://www.axis-shield.com/
510(k) history	24 submissions · 24 cleared · 2002-2026

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