

**K041866 ABBOTT AXSYM TESTOSTERONE MICROPARTICLE
ENZYME IMMUNOASSAY (MEIA)**Sep 29, 2004
82 days to decisionK041866 · Product code: **CDZ** · Chemistry
Source: <https://www.510kdatabase.net/k041866/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Testosterones And Dihydrotestosterone (CDZ)
Date received	Jul 9, 2004
Decision date	Sep 29, 2004
Days to decision	82 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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