

**K042411 ABBOTT IMX SIROLIMUS MICROPARTICLE ENZYME
IMMUNOASSAY**Apr 7, 2005
212 days to decisionK042411 · Product code: **NRP** · Toxicology
Source: <https://www.510kdatabase.net/k042411/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sirolimus Test System (NRP)
Date received	Sep 7, 2004
Decision date	Apr 7, 2005
Days to decision	212 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Axis-Shield , Ltd.
Location	Dundee, GB
Contact	SUSAN LEONARD
510(k) history	2 submissions · 2 cleared · 2000-2005

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k042411/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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