

K070822 ARCHITECT SIROLIMUS ASSAYSep 28, 2007
186 days to decisionK070822 · Product code: **NRP** · Toxicology
Source: <https://www.510kdatabase.net/k070822/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sirolimus Test System (NRP)
Date received	Mar 26, 2007
Decision date	Sep 28, 2007
Days to decision	186 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fujirebio Diagnostics, Inc.
Location	North Caldwell, NJ, US
Contact	DIANA LYN DICKSON
510(k) history	45 submissions · 43 cleared · 1989-2025

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