

**K150168 Dimension Tacrolimus Flex® Reagent Cartridge (TAC),
Dimension Tacrolimus Calibrator (TAC CAL)**Nov 4, 2015
282 days to decisionK150168 · Product code: MLM · Toxicology
Source: <https://www.510kdatabase.net/k150168/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Tacrolimus (MLM)
Date received	Jan 26, 2015
Decision date	Nov 4, 2015
Days to decision	282 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthcare Diagnostics
Location	Newark, DE, US
Contact	Anna Marie Kathleen Ennis
510(k) history	92 submissions · 92 cleared · 2008-2025

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