CLEARED

K083487 EMIT 2000 SIROLIMUS ASSAY, EMIT 2000 SIRO/TACRO SAMPLE PRETREATMENT REAGENT, AND EMIT 200 SIROLIMUS CALIBRATOR

Mar 30, 2009
125 days to decision

K083487 · Product code: **NRP** · Toxicology
Source: https://www.510kdatabase.net/k083487/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sirolimus Test System (NRP)
Date received	Nov 25, 2008
Decision date	Mar 30, 2009
Days to decision	125 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Siemens Healthcare Diagnostics**
Location	Newark, DE, US
Contact	YUK-TING LEWIS
510(k) history	92 submissions · 92 cleared · 2008-2025