FDA 510(k) Premarket Notification

CLEARED

K111335 ST AIA-PACK ACTH, AND ST AIA-PACK ACTH CALIBRATOR SET MODEL 025221 AND 025321

Dec 1, 2011
203 days to decision

K111335 · Product code: **CKG** · Chemistry
Source: https://www.510kdatabase.net/k111335/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Acth (CKG)
Date received	May 12, 2011
Decision date	Dec 1, 2011
Days to decision	203 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Tosoh Bioscience, Inc.**
Location	Grove City, OH, US
Contact	JUDITH K OGDEN
510(k) history	20 submissions · 20 cleared · 2007-2025