

K160113 ST AIA-PACK hsE2 Calibrator SetFeb 17, 2016
29 days to decisionK160113 · Product code: **JIT** · Chemistry
Source: <https://www.510kdatabase.net/k160113/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Secondary (JIT)
Date received	Jan 19, 2016
Decision date	Feb 17, 2016
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Tosoh Bioscience, Inc.
Location	Grove City, OH, US
Contact	ROBERT L WICK
510(k) history	20 submissions · 20 cleared · 2007-2025

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