

K063605 ST AIA-PACK INTACT PTH ASSAYJun 21, 2007
199 days to decisionK063605 · Product code: **CEW** · Chemistry
Source: <https://www.510kdatabase.net/k063605/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Parathyroid Hormone (CEW)
Date received	Dec 4, 2006
Decision date	Jun 21, 2007
Days to decision	199 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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