

**K143075 ST AIA-PACK SHBG, ST AIA-PACK SHBG Calibrator Set**

Jul 2, 2015  
248 days to decision

K143075 · Product code: **CDZ** · Chemistry  
Source: <https://www.510kdatabase.net/k143075/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Testosterones And Dihydrotestosterone (CDZ)
Date received	Oct 27, 2014
Decision date	Jul 2, 2015
Days to decision	248 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k143075/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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