

K151529 Dimension Vista LOCI Total Testosterone Flex reagent cartridge, Dimension Vista Testosterone CalibratorFeb 11, 2016
248 days to decisionK151529 · Product code: **CDZ** · Chemistry
Source: <https://www.510kdatabase.net/k151529/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Testosterones And Dihydrotestosterone (CDZ)
Date received	Jun 8, 2015
Decision date	Feb 11, 2016
Days to decision	248 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthcare Diagnostics, Inc.
Location	New York, NY, US
Contact	JULIE WARREN
Website	https://www.siemens-healthineers.com
510(k) history	152 submissions · 151 cleared · 2008-2026

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