FDA 510(k) Premarket Notification

K120009 TESTOSTERONE TEST SYSTEM

CLEARED

Sep 11, 2012
252 days to decision

K120009 · Product code: **CDZ** · Chemistry
Source: https://www.510kdatabase.net/k120009/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Testosterones And Dihydrotestosterone (CDZ)
Date received	Jan 3, 2012
Decision date	Sep 11, 2012
Days to decision	252 days
Third-party review	No
Summary / Statement	Summary
Other names	CALIBRATOR; AND QUALITY CONTROL MATERIAL (ASSAYED AND UNASSAYED)

APPLICANT

Company	**Abbott Laboratories**
Location	Abbott Park, IL, US
Contact	JOHN RIZOS
Website	http://www.abbott.com
510(k) history	883 submissions · 868 cleared · 1976-2026

Abbott Laboratories is an American multinational medical devices and health care company headquartered in Abbott Park, Illinois. The company operates in over 160 countries and produces pharmaceuticals, diagnostics, nutritional products, and medical devices. Abbott maintains a substantial FDA 510(k) regulatory record with FDA 510(k) cleared devices from total submissions since 1976. The company's cleared devices span chemistry, microbiology, hematology, immunology, and toxicology categories. The latest clearance in 2025 reflects continued regulatory activity and product de...