

K153375 ARCHITECT 25-OH Vitamin D 5P02, ARCHITECT 25-OH Vitamin D 5P02 Calibrators, ARCHITECT 25-OH Vitamin D 5P02 ControlsAug 12, 2016
263 days to decisionK153375 · Product code: **MRG** · Chemistry
Source: <https://www.510kdatabase.net/k153375/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Vitamin D (MRG)
Date received	Nov 23, 2015
Decision date	Aug 12, 2016
Days to decision	263 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Abbott Laboratories
Location	Abbott Park, IL, US
Contact	LAURA YELVIGI JOGLEKAR
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...