

K152185 ARCHITECT SHBGFeb 11, 2016
190 days to decisionK152185 · Product code: **CDZ** · Chemistry
Source: <https://www.510kdatabase.net/k152185/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Testosterones And Dihydrotestosterone (CDZ)
Date received	Aug 5, 2015
Decision date	Feb 11, 2016
Days to decision	190 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biokit, S.A.
Location	Barcelona, ES
Contact	ANGELS ROMA
510(k) history	23 submissions · 23 cleared · 2005-2025

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