

K031717 ELECSYS SHBG IMMUNOASSAYAug 5, 2003
63 days to decisionK031717 · Product code: **CDZ** · Chemistry
Source: <https://www.510kdatabase.net/k031717/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Testosterones And Dihydrotestosterone (CDZ)
Date received	Jun 3, 2003
Decision date	Aug 5, 2003
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics Corp.
Location	Indianapolis, IN, US
Contact	THERESA M AMBROSE
510(k) history	264 submissions · 263 cleared · 1999-2013

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