

K190121 IDS SHBGJun 17, 2019
143 days to decisionK190121 · Product code: **CDZ** · Chemistry
Source: <https://www.510kdatabase.net/k190121/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Testosterones And Dihydrotestosterone (CDZ)
Date received	Jan 25, 2019
Decision date	Jun 17, 2019
Days to decision	143 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Immunodiagnostic Systems , Ltd.
Location	Tyne And Wear, GB
Contact	Mick Henderson
510(k) history	23 submissions · 23 cleared · 1994-2021

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