

K252728 IDS-iSYS Total TestosteroneApr 15, 2026
230 days to decisionK252728 · Product code: **CDZ** · Chemistry
Source: <https://www.510kdatabase.net/k252728/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Testosterones And Dihydrotestosterone (CDZ)
Date received	Aug 28, 2025
Decision date	Apr 15, 2026
Days to decision	230 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Immunodiagnostic Systems Limited
Location	Boldon, GB
Contact	Mick Henderson
510(k) history	3 submissions · 3 cleared · 2023-2026

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