

K973900 TESTOTERONE ELISAFeb 24, 1998
133 days to decisionK973900 · Product code: **CDZ** · Chemistry
Source: <https://www.510kdatabase.net/k973900/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Testosterones And Dihydrotestosterone (CDZ)
Date received	Oct 14, 1997
Decision date	Feb 24, 1998
Days to decision	133 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Kmi Diagnostics, Inc.
Location	Minneapolis, MN, US
Contact	MARK A KOWAL
510(k) history	6 submissions · 6 cleared · 1997-2002

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