

**K955102 BIODATA TESTOSTERONE MAIA KIT**Jun 24, 1996  
229 days to decisionK955102 · Product code: **CDZ** · Chemistry  
Source: <https://www.510kdatabase.net/k955102/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Testosterones And Dihydrotestosterone (CDZ)
Date received	Nov 8, 1995
Decision date	Jun 24, 1996
Days to decision	229 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biochem Immunosystems (U.S.), Inc.</b>
Location	Allentown, PA, US
Contact	LAURENCE A POTTER
510(k) history	4 submissions · 4 cleared · 1996-1997

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