

K915164 SRI TESTOSTERONE ENZYME IMMUNOASSAYMar 2, 1992
109 days to decisionK915164 · Product code: **CDZ** · Chemistry
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Testosterones And Dihydrotestosterone (CDZ)
Date received	Nov 14, 1991
Decision date	Mar 2, 1992
Days to decision	109 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Serono-Baker Diagnostics, Inc.
Location	Winchester, VA, US
Contact	DAVID B THOMAS
510(k) history	23 submissions · 23 cleared · 1988-1992

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