

K800776 TESTOK-125Apr 21, 1980
14 days to decisionK800776 · Product code: **CDZ** · Chemistry
Source: <https://www.510kdatabase.net/k800776/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Testosterones And Dihydrotestosterone (CDZ)
Date received	Apr 7, 1980
Decision date	Apr 21, 1980
Days to decision	14 days
Third-party review	No

APPLICANT

Company	Sorin Biomedica, Fiat, USA, Inc.
Location	Mchenry, IL, US
510(k) history	20 submissions · 20 cleared · 1980-1994

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Device record: <https://www.510kdatabase.net/k800776/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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