

K841948 TESTOSTERONE DIRECT RADIOIMMUNOASSAYJun 25, 1984
42 days to decisionK841948 · Product code: **CDZ** · Chemistry
Source: <https://www.510kdatabase.net/k841948/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Radioimmunoassay, Testosterones And Dihydrotestosterone (CDZ) |
| Date received | May 14, 1984 |
| Decision date | Jun 25, 1984 |
| Days to decision | 42 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 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k841948/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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