

K942051 SR1 DHEA-S ENZYME IMMUNOASSAYJul 13, 1994
76 days to decisionK942051 · Product code: **JKC** · Toxicology
Source: <https://www.510kdatabase.net/k942051/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Dehydroepiandrosterone (free And Sulfate) (JKC)
Date received	Apr 28, 1994
Decision date	Jul 13, 1994
Days to decision	76 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Serono Diagnostics, Inc.
Location	Walker, MI, US
Contact	RICHARD D ECKLOFF
510(k) history	25 submissions · 25 cleared · 1984-1996

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k942051/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026