

K953066 SERODIA ATGAug 14, 1995
45 days to decisionK953066 · Product code: **DDC** · Immunology
Source: <https://www.510kdatabase.net/k953066/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thyroglobulin, Antigen, Antiserum, Control (DDC)
Date received	Jun 30, 1995
Decision date	Aug 14, 1995
Days to decision	45 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Fujirebio America, Inc.
Location	Fairfield, NJ, US
Contact	ROBERT SCJOFF
510(k) history	2 submissions · 2 cleared · 1991-1995

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