

K953671 ORGEN TEC ANTI-DSDNA ELISA ASSAYNov 9, 1995
94 days to decisionK953671 · Product code: **LRM** · Immunology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti-dna Antibody (enzyme-labeled), Antigen, Control (LRM)
Date received	Aug 7, 1995
Decision date	Nov 9, 1995
Days to decision	94 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Orgentec
Location	Windham, NH, US
Contact	RICHARD CONLEY
510(k) history	10 submissions · 10 cleared · 1995-1996

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