

K955133 ORGENTEC ENASCREEN PIN IMMUNO ASSAYMar 20, 1996
132 days to decisionK955133 · Product code: LLL · Immunology
Source: <https://www.510kdatabase.net/k955133/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Nov 9, 1995
Decision date	Mar 20, 1996
Days to decision	132 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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