

K954830 ORGENTEC ANTI-SM(SMITH) PIN IMMUNO ASSAYMay 8, 1996
201 days to decisionK954830 · Product code: **LKP** · Immunology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti-sm Antibody, Antigen And Control (LKP)
Date received	Oct 20, 1995
Decision date	May 8, 1996
Days to decision	201 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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