

K923537 ENCORE DS-DNADec 23, 1992
160 days to decisionK923537 · 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	Jul 16, 1992
Decision date	Dec 23, 1992
Days to decision	160 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Clark Laboratories, Inc.
Location	Blairstown, NJ, US
Contact	Gary Lehnus
510(k) history	14 submissions · 14 cleared · 1992-1998

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