

K051066 THERATEST EL-ANA PROFILESOct 7, 2005
164 days to decisionK051066 · Product code: **LKP** · Immunology
Source: <https://www.510kdatabase.net/k051066/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti-sm Antibody, Antigen And Control (LKP)
Date received	Apr 26, 2005
Decision date	Oct 7, 2005
Days to decision	164 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Theratest Laboratories, Inc.
Location	Chicago, IL, US
Contact	MARIUS TEDORESCU
510(k) history	22 submissions · 22 cleared · 1991-2010

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