

K000312 VARELISA SM ANTIBODIESMar 17, 2000
45 days to decisionK000312 · Product code: **LKP** · Immunology
Source: <https://www.510kdatabase.net/k000312/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti-sm Antibody, Antigen And Control (LKP)
Date received	Feb 1, 2000
Decision date	Mar 17, 2000
Days to decision	45 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Pharmacia & Upjohn Co.
Location	Westerville, OH, US
Contact	KAREN MATIS
510(k) history	18 submissions · 18 cleared · 1996-2000

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