

K050419 QMS VANCOMYCINApr 1, 2005
42 days to decisionK050419 · Product code: **LEH** · Toxicology
Source: <https://www.510kdatabase.net/k050419/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Vancomycin (LEH)
Date received	Feb 18, 2005
Decision date	Apr 1, 2005
Days to decision	42 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Seradyn, Inc.
Location	Indianapolis, IN, US
Contact	JACK ROGERS
510(k) history	28 submissions · 28 cleared · 1988-2007

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