

K123947 ARCHITECT IVANCOMYCINAug 29, 2013
251 days to decisionK123947 · Product code: **LEH** · Toxicology
Source: <https://www.510kdatabase.net/k123947/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Vancomycin (LEH)
Date received	Dec 21, 2012
Decision date	Aug 29, 2013
Days to decision	251 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biokit, S.A.
Location	Barcelona, ES
Contact	GUILLEM ANGLERILL
510(k) history	23 submissions · 23 cleared · 2005-2025

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