

**K072036 ARCHITECT IVANCOMYCIN REAGENTS AND  
ARCHITECT IVANCOMYCIN CALIBRATORS, MODELS: 1P30-25  
AND 1P30-01**Mar 19, 2008  
238 days to decisionK072036 · Product code: LEH · Toxicology  
Source: <https://www.510kdatabase.net/k072036/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Vancomycin (LEH)
Date received	Jul 25, 2007
Decision date	Mar 19, 2008
Days to decision	238 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Biokit, S.A.</b>
Location	Barcelona, ES
Contact	JOAN GUIXER
510(k) history	23 submissions · 23 cleared · 2005-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k072036/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 25, 2026