

**K082141 ARCHITECT C-PEPTIDE CALIBRATORS, AND  
ARCHITECT C-PEPTIDE CONTROLS, MODELS 3L53-01, 3L53-10**Sep 3, 2008  
35 days to decisionK082141 · Product code: JIT · Chemistry  
Source: <https://www.510kdatabase.net/k082141/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Calibrator, Secondary (JIT)
Date received	Jul 30, 2008
Decision date	Sep 3, 2008
Days to decision	35 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k082141/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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