

**K063232 ARCHITECT INTACT PTH REAGENTS, CALIBRATORS
(A-F) AND CONTROLS (LOW, MEDIUM, HIGH), MODELS
8K25-20, 8K25-25, 8K25-01**Jun 19, 2007
237 days to decisionK063232 · Product code: **CEW** · Chemistry
Source: <https://www.510kdatabase.net/k063232/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Parathyroid Hormone (CEW)
Date received	Oct 25, 2006
Decision date	Jun 19, 2007
Days to decision	237 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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