

**K243575 ARCHITECT HSV-2 IgG, ARCHITECT HSV-2 IgG Calibrator, ARCHITECT HSV-2 IgG Controls**

Feb 12, 2025  
85 days to decision

K243575 · Product code: MYF · Microbiology  
Source: <https://www.510kdatabase.net/k243575/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunosorbent Assay, Herpes Simplex Virus, Hsv-2 (MYF)
Date received	Nov 19, 2024
Decision date	Feb 12, 2025
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biokit, S.A.</b>
Location	Barcelona, ES
Contact	Janna Puig
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/k243575/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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