

K213987 ARCHITECT HSV-1 IgG, ARCHITECT HSV-1 IgG Calibrator, ARCHITECT HSV-1 IgG Controls

Sep 20, 2023
639 days to decision

K213987 · Product code: **MXJ** · Microbiology
Source: <https://www.510kdatabase.net/k213987/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunosorbent Assay, Herpes Simplex Virus, Hsv-1 (MXJ)
Date received	Dec 20, 2021
Decision date	Sep 20, 2023
Days to decision	639 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k213987/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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