

K233606 ADVIA Centaur EBV-VCA IgMAug 7, 2024
272 days to decisionK233606 · Product code: **LSE** · Microbiology
Source: <https://www.510kdatabase.net/k233606/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Epstein-barr Virus, Other (LSE)
Date received	Nov 9, 2023
Decision date	Aug 7, 2024
Days to decision	272 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233606/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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