

K181334 ADVIA Centaur Herpes-2 IgGAug 23, 2018
94 days to decisionK181334 · Product code: **MYF** · Microbiology
Source: <https://www.510kdatabase.net/k181334/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunosorbent Assay, Herpes Simplex Virus, Hsv-2 (MYF)
Date received	May 21, 2018
Decision date	Aug 23, 2018
Days to decision	94 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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