

K033106 CAPTIA HSV 2 IGG TYPE SPECIFIC ELISA KITJul 13, 2004
287 days to decisionK033106 · Product code: **MYF** · Microbiology
Source: <https://www.510kdatabase.net/k033106/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunosorbent Assay, Herpes Simplex Virus, Hsv-2 (MYF)
Date received	Sep 30, 2003
Decision date	Jul 13, 2004
Days to decision	287 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Trinity Biotech USA
Location	Jamestown, NY, US
Contact	Bonnie B DeJoy
510(k) history	11 submissions · 11 cleared · 1999-2014

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