

K021486 HERPESELECT 2 ELISA IGG, MODEL ELO920GAug 1, 2002
90 days to decisionK021486 · Product code: **MXJ** · Microbiology
Source: <https://www.510kdatabase.net/k021486/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunosorbent Assay, Herpes Simplex Virus, Hsv-1 (MXJ)
Date received	May 3, 2002
Decision date	Aug 1, 2002
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Focus Technologies, Inc.
Location	Cypress, CA, US
Contact	MICHAEL J WAGNER
510(k) history	5 submissions · 5 cleared · 2002-2004

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