

K071510 HERPESELECT EXPRESS IGG, HERPESELECT EXPRESS CONTROLS, MODELS RT0920G, RT0950Sep 24, 2007
112 days to decisionK071510 · Product code: **MXJ** · Microbiology
Source: <https://www.510kdatabase.net/k071510/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunosorbent Assay, Herpes Simplex Virus, Hsv-1 (MXJ)
Date received	Jun 4, 2007
Decision date	Sep 24, 2007
Days to decision	112 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Focus Diagnostics, Inc.
Location	Cypress, CA, US
Contact	CONSTANCE BRIDGES
510(k) history	14 submissions · 13 cleared · 2007-2015

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