

K062543 HERPESELECT 1 AND 2 PLEXUS IGG, MODEL MP0900GFeb 1, 2007
155 days to decisionK062543 · Product code: **MXJ** · Microbiology
Source: <https://www.510kdatabase.net/k062543/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunosorbent Assay, Herpes Simplex Virus, Hsv-1 (MXJ)
Date received	Aug 30, 2006
Decision date	Feb 1, 2007
Days to decision	155 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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