

**K073381 PLEXUS EBV IGM MULTI-ANALYTE DIAGNOSTICS,
MODEL: MP0600M**Aug 4, 2008
245 days to decisionK073381 · Product code: **LJN** · Microbiology
Source: <https://www.510kdatabase.net/k073381/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Antibody Igm, If, Epstein-barr Virus (LJN) |
| Date received | Dec 3, 2007 |
| Decision date | Aug 4, 2008 |
| Days to decision | 245 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 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k073381/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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