

**K923903 VITEK IMMUNODIAGNOSTIC ASSAY SYSTEM MUMPS
IGG ASSA**

Aug 9, 1993
370 days to decision

K923903 · Product code: **LJY** · Microbiology
Source: <https://www.510kdatabase.net/k923903/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Mumps Virus (LJY)
Date received	Aug 4, 1992
Decision date	Aug 9, 1993
Days to decision	370 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biomerieux Vitek, Inc.
Location	Hazelwood, MO, US
Contact	CHERYL WINTERS-HEARD
510(k) history	49 submissions · 49 cleared · 1992-1998

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k923903/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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