

**K912231 PROPOSED NEW USE OF INSTRUMENT SYSTEM AND TEST KIT**Jul 8, 1991  
49 days to decisionK912231 · Product code: **JHW** · Chemistry  
Source: <https://www.510kdatabase.net/k912231/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	U.v. Method, Cpk Isoenzymes (JHW)
Date received	May 20, 1991
Decision date	Jul 8, 1991
Days to decision	49 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Intl. Immunoassay Laboratories, Inc.</b>
Location	Mchenry, IL, US
Contact	VIPIN D SHAH
510(k) history	27 submissions · 27 cleared · 1980-1992

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k912231/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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