

**K053566 MODIFICATION TO: DIAZYME POTASSIUM  
ENZYMATIC ASSAY, MODEL DZ113A**Feb 15, 2006  
55 days to decisionK053566 · Product code: **MZV** · Chemistry  
Source: <https://www.510kdatabase.net/k053566/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Test, System, Potassium, Enzymatic Method (MZV)
Date received	Dec 22, 2005
Decision date	Feb 15, 2006
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Diazyme Laboratories</b>
Location	Irvine, CA, US
Contact	HUAN TRAN
510(k) history	41 submissions · 41 cleared · 2003-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k053566/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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