

K042189 DIAZYME SODIUM ENZYMATIC ASSAYOct 7, 2004
56 days to decisionK042189 · Product code: **MZU** · Chemistry
Source: <https://www.510kdatabase.net/k042189/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Sodium, Enzymatic Method (MZU)
Date received	Aug 12, 2004
Decision date	Oct 7, 2004
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Diazyme Laboratories
Location	Irvine, CA, US
Contact	HUHAN TRAN
510(k) history	41 submissions · 41 cleared · 2003-2018

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