

**K080057 IMDX ANALYZER, IMDXPREP REAGENT PLATE,
IMDXPREP CALIBRATION PLATE, IMDXPREP CONTROL**Oct 31, 2008
296 days to decisionK080057 · Product code: **DKZ** · Chemistry
Source: <https://www.510kdatabase.net/k080057/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Amphetamine (DKZ)
Date received	Jan 9, 2008
Decision date	Oct 31, 2008
Days to decision	296 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Novx Systems, Inc.
Location	Rockville, MD, US
Contact	THOMAS TSAKERIS
510(k) history	2 submissions · 2 cleared · 2007-2008

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