

K063699 IMDX SYSTEMSJun 1, 2007
170 days to decisionK063699 · Product code: **DJG** · Chemistry
Source: <https://www.510kdatabase.net/k063699/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Dec 13, 2006
Decision date	Jun 1, 2007
Days to decision	170 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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