

**K974840 ABUSCREEN ONLINE II FOR OPIATES 300/2000,
ABUSCREEN ONLINE OPIATES CALIBRATION PACK,
ABUSCREEN ONLINE OPIATES CONTROL**Apr 24, 1998
121 days to decisionK974840 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k974840/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Dec 24, 1997
Decision date	Apr 24, 1998
Days to decision	121 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostic Systems, Inc.
Location	Mchenry, IL, US
Contact	JAMES W HAYNES
510(k) history	296 submissions · 296 cleared · 1983-1999

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