

K943712 VERDICT OPIATESNov 17, 1994
108 days to decisionK943712 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k943712/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Aug 1, 1994
Decision date	Nov 17, 1994
Days to decision	108 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Editek, Inc.
Location	Burlington, NC, US
Contact	CAROL GOLDEN
510(k) history	7 submissions · 7 cleared · 1994-1996

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