

**K003209 URINE OPIATES (OPI) SCREEN FLEX REAGENT
CARTRIDGE, CATALOG NO. DF93A**Dec 5, 2000
53 days to decisionK003209 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k003209/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Oct 13, 2000
Decision date	Dec 5, 2000
Days to decision	53 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dade Behring, Inc.
Location	Newark,, DE, US
Contact	CATHY P CRAFT
510(k) history	343 submissions · 343 cleared · 1978-2010

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