

**K000464 URINE OPIATES (OPI) SCREEN FLEX REAGENT
CARTRIDGE, CATALOG NO. DF 90A**Apr 14, 2000
63 days to decisionK000464 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k000464/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Feb 11, 2000
Decision date	Apr 14, 2000
Days to decision	63 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dade Behring, Inc.
Location	Newark,, DE, US
Contact	JUDY MCINNIS-BERGER
510(k) history	343 submissions · 343 cleared · 1978-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k000464/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 19, 2026