

**K000459 URINE BARBITURATES (BARB) SCREEN FLEX  
REAGENT CARTRIDGE, CATALOG NO. DF 96A**Apr 3, 2000  
52 days to decisionK000459 · Product code: **DIS** · Toxicology  
Source: <https://www.510kdatabase.net/k000459/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Barbiturate (DIS)
Date received	Feb 11, 2000
Decision date	Apr 3, 2000
Days to decision	52 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k000459/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 19, 2026