

**K032564 DIMENSION N-ACETYLPROCAINAMIDE (NAPA) FLEX
REAGENT CARTRIDGE METHOD, MODEL DF111**Oct 31, 2003
72 days to decisionK032564 · Product code: LAN · Chemistry
Source: <https://www.510kdatabase.net/k032564/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, N-acetylprocainamide (LAN)
Date received	Aug 20, 2003
Decision date	Oct 31, 2003
Days to decision	72 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dade Behring, Inc.
Location	Newark,, DE, US
Contact	RICHARD M VAUGHT
510(k) history	343 submissions · 343 cleared · 1978-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k032564/> 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