

K003963 DIMENSION PSA FLEX REAGENT CARTRIDGEFeb 28, 2001
68 days to decisionK003963 · Product code: **LTJ** · Immunology
Source: <https://www.510kdatabase.net/k003963/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prostate-specific Antigen (psa) For Management Of Prostate Cancers (LTJ)
Date received	Dec 22, 2000
Decision date	Feb 28, 2001
Days to decision	68 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k003963/> 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