

K031343 TPSA FLEX REAGENT CARTRIDGEMay 15, 2003
16 days to decisionK031343 · Product code: **LTJ** · Immunology
Source: <https://www.510kdatabase.net/k031343/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prostate-specific Antigen (psa) For Management Of Prostate Cancers (LTJ)
Date received	Apr 29, 2003
Decision date	May 15, 2003
Days to decision	16 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

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