

**K010550 VIDAS TOTAL PROSTATE SPECIFIC ANTIGEN (TPSA),
MODEL 30 428**Apr 24, 2001
57 days to decisionK010550 · Product code: **LTJ** · Immunology
Source: <https://www.510kdatabase.net/k010550/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prostate-specific Antigen (psa) For Management Of Prostate Cancers (LTJ)
Date received	Feb 26, 2001
Decision date	Apr 24, 2001
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	bioMerieux, Inc.
Location	Mchenry, IL, US
Contact	Nancy Weaver
510(k) history	251 submissions · 250 cleared · 1983-2026

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