CLEARED

K000566 MODOFICATION TO VITRO IMMUNODIAGNOSTIC PRODUCTS PSA REAGENT PACK, VITRO IMMUNODIAGNOSTIC PRODUCTS PSA CALIBRATORS

Mar 9, 2000
16 days to decision

K000566 · Product code: **LTJ** · Immunology
Source: https://www.510kdatabase.net/k000566/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prostate-specific Antigen (psa) For Management Of Prostate Cancers (LTJ)
Date received	Feb 22, 2000
Decision date	Mar 9, 2000
Days to decision	16 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ortho-Clinical Diagnostics, Inc.**
Location	Rochester, NY, US
Contact	JOSEPH FALVO
510(k) history	106 submissions · 104 cleared · 1997-2025