K022177 PROSTATE SPECIFIC ANTIGEN (PSA) ASSAY FOR THE ADVIA INTEGRATED MODULAR SYSTEM

CLEARED

Dec 17, 2002
167 days to decision

K022177 · Product code: **LTJ** · Immunology
Source: https://www.510kdatabase.net/k022177/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prostate-specific Antigen (psa) For Management Of Prostate Cancers (LTJ)
Date received	Jul 3, 2002
Decision date	Dec 17, 2002
Days to decision	167 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bayer Diagnostics Corp.**
Location	Medfield, MA, US
Contact	KENNETH T EDDS
510(k) history	32 submissions · 32 cleared · 2000-2003