K012183 BAYER DIAGNOSTICS ADVIA CENTAUR TOXOPLASMA IGG ASSAY

CLEARED

Dec 27, 2001
168 days to decision

K012183 · Product code: **LGD** · Microbiology
Source: https://www.510kdatabase.net/k012183/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Toxoplasma Gondii (LGD)
Date received	Jul 12, 2001
Decision date	Dec 27, 2001
Days to decision	168 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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