FDA 510(k) Premarket Notification

K950671 IMMULITE TOXOPLASMA GONDII IGG

CLEARED

Feb 23, 1996
375 days to decision

K950671 · Product code: **LGD** · Microbiology
Source: https://www.510kdatabase.net/k950671/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Toxoplasma Gondii (LGD)
Date received	Feb 13, 1995
Decision date	Feb 23, 1996
Days to decision	375 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Diagnostic Products Corp.**
Location	Mchenry, IL, US
Contact	KENNETH ASARCH
510(k) history	321 submissions · 321 cleared · 1976-2006