FDA 510(k) Premarket Notification

K962936 IMMULITE TOXOPLASMA QUANTITATIVE IGG

CLEARED

Apr 24, 1997
269 days to decision

K962936 · Product code: **LGD** · Microbiology
Source: https://www.510kdatabase.net/k962936/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Toxoplasma Gondii (LGD)
Date received	Jul 29, 1996
Decision date	Apr 24, 1997
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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