

K842528 AMIZYME-TOXOPLASMA GONDII KITSep 7, 1984
71 days to decisionK842528 · Product code: **LGD** · Microbiology
Source: <https://www.510kdatabase.net/k842528/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Toxoplasma Gondii (LGD)
Date received	Jun 28, 1984
Decision date	Sep 7, 1984
Days to decision	71 days
Third-party review	No

APPLICANT

Company	Amico Lab, Inc.
Location	Mchenry, IL, US
510(k) history	32 submissions · 32 cleared · 1982-1985

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Device record: <https://www.510kdatabase.net/k842528/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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