CLEARED

K002453 ACCESS TOXO IGM II REAGENTS FOR USE ON THE ACCESS IMMUNOASSAY SYSTEMS, MODELS 34470, 34475, AND 34479

Aug 31, 2000
21 days to decision

K002453 · Product code: **LGD** · Microbiology
Source: https://www.510kdatabase.net/k002453/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Enzyme Linked Immunoabsorbent Assay, Toxoplasma Gondii (LGD)
Date received	Aug 10, 2000
Decision date	Aug 31, 2000
Days to decision	21 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Beckman Coulter, Inc.**
Location	Chaska, MN, US
Contact	JAN OLSEN
Website	https://www.beckmancoulter.com
510(k) history	270 submissions · 270 cleared · 1993-2026

Beckman Coulter, Inc. is a diagnostic device manufacturer headquartered in Chaska, US. The company specializes in clinical laboratory and immunodiagnostic systems. Beckman Coulter has received FDA 510(k) clearances from total submissions since its first clearance in 1993. The company maintains active regulatory status, with the latest clearance in 2026. Its portfolio spans chemistry devices, microbiology testing systems, hematology analyzers, and immunoassay platforms. Recent cleared devices include chemistry assays for cardiac markers, microbiology susceptibility panels,...