

K003306 C. DIFFICILE TOX A/B IINov 22, 2000
33 days to decisionK003306 · Product code: LLH · Microbiology
Source: <https://www.510kdatabase.net/k003306/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Reagents, Clostridium Difficile Toxin (LLH)
Date received	Oct 20, 2000
Decision date	Nov 22, 2000
Days to decision	33 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Techlab, Inc.
Location	Blacksburg, VA, US
Contact	DAVID M LYERLY
Website	http://www.techlab.com/
510(k) history	36 submissions · 36 cleared · 1992-2019

Techlab, Inc. designs, develops, and manufactures infectious disease diagnostics in the USA. The company specializes in enteric and microbiology diagnostic products distributed worldwide. Techlab holds ISO 13485 certification and MDSAP approval with FDA registration. Techlab received FDA 510(k) clearances from total submissions between 1992 and 2019. The company's portfolio is dominated by microbiology devices, representing 83% of submissions. Notable cleared products include tests for Clostridioides difficile, Helicobacter pylori, parasites, and fecal biomarkers. Techlab...
