FDA 510(k) Premarket Notification

K931241 FAST'N'FLAMMATORY KIT

CLEARED

Feb 3, 1994
329 days to decision

K931241 · Product code: **GIA** · Hematology
Source: https://www.510kdatabase.net/k931241/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Leukocyte Peroxidase (GIA)
Date received	Mar 11, 1993
Decision date	Feb 3, 1994
Days to decision	329 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Techlab, Inc.**
Location	Blacksburg, VA, US
Contact	TRACY WILKINS
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...