FDA 510(k) Premarket Notification

K955897 CRYPTO/GIARDIA-CEL IF TEST

CLEARED

Aug 5, 1996
223 days to decision

K955897 · Product code: **MHI** · Microbiology
Source: https://www.510kdatabase.net/k955897/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Giardia Spp. (MHI)
Date received	Dec 26, 1995
Decision date	Aug 5, 1996
Days to decision	223 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...