FDA 510(k) Premarket Notification

K191456 Campylobacter Quik Chek

CLEARED

Jun 20, 2019
20 days to decision

K191456 · Product code: **LQP** · Microbiology
Source: https://www.510kdatabase.net/k191456/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Campylobacter Spp. (LQP)
Date received	May 31, 2019
Decision date	Jun 20, 2019
Days to decision	20 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Techlab, Inc.**
Location	Blacksburg, VA, US
Contact	Donna Link
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...