FDA 510(k) Premarket Notification

K103673 GIARDIA/ CRYPTOSPORIDIUM QUIK CHEK

CLEARED

Aug 18, 2011
245 days to decision

K103673 · Product code: **MHI** · Microbiology
Source: https://www.510kdatabase.net/k103673/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Giardia Spp. (MHI)
Date received	Dec 16, 2010
Decision date	Aug 18, 2011
Days to decision	245 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Techlab Inc., Corporate Research Center**
Location	Blacksburg, VA, US
Contact	DONNA T LINK
510(k) history	5 submissions · 5 cleared · 2007-2012