FDA 510(k) Premarket Notification

K031942 XPECT GIARDIA LATERAL FLOW ASSAY, MODEL 2450020

CLEARED

Nov 18, 2003
147 days to decision

K031942 · Product code: **MHI** · Microbiology
Source: https://www.510kdatabase.net/k031942/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Giardia Spp. (MHI)
Date received	Jun 24, 2003
Decision date	Nov 18, 2003
Days to decision	147 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Remel, Inc.**
Location	Lenexa, KS, US
Contact	RICHARD TYSON
510(k) history	17 submissions · 17 cleared · 1994-2017