

K141341 CL DETECT RAPID TESTNov 14, 2014
177 days to decisionK141341 · Product code: **PIT** · Microbiology
Source: <https://www.510kdatabase.net/k141341/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Leishmania Spp. Antigen Detection Assay (PIT)
Date received	May 21, 2014
Decision date	Nov 14, 2014
Days to decision	177 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	InBios International, Inc.
Location	Seattle, WA, US
Contact	ESTELA RAYCHAUDHURI
510(k) history	7 submissions · 5 cleared · 2014-2025

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