

K023483 KALAZAR DETECTMay 6, 2003
201 days to decisionK023483 · Product code: **LOO** · Microbiology
Source: <https://www.510kdatabase.net/k023483/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Leishmanii Serological (LOO)
Date received	Oct 17, 2002
Decision date	May 6, 2003
Days to decision	201 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Inbios Intl., Inc.
Location	Seattle, WA, US
Contact	ESTELA I RAYCHAUDHURI
510(k) history	6 submissions · 5 cleared · 1999-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k023483/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026