

K081868 SMART LEISH, MODEL LGM1-050May 25, 2011
1057 days to decisionK081868 · Product code: **OUZ** · Microbiology
Source: <https://www.510kdatabase.net/k081868/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nucleic Amplification Assays For The Detection Of Leishmania Nucleic Acids (OUZ)
Date received	Jul 2, 2008
Decision date	May 25, 2011
Days to decision	1057 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	U.S. Army Medical Research Institute of Infectious
Location	Fort Detrick, MD, US
Contact	ROBER MILLER
510(k) history	1 submissions · 1 cleared · 2011-2011

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