

K053570 TREP-SURE TREPONEMAL ANTIBODY EIAAug 7, 2006
228 days to decisionK053570 · Product code: **LIP** · Microbiology
Source: <https://www.510kdatabase.net/k053570/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorption Assay, Treponema Pallidum (LIP)
Date received	Dec 22, 2005
Decision date	Aug 7, 2006
Days to decision	228 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Phoenix Biotech Corp.
Location	Blairstown, NJ, US
Contact	Gary Lehnus
510(k) history	2 submissions · 2 cleared · 2000-2006

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