

K001552 TREPCHek TREPONEMAL ANTIBODY EIAOct 19, 2000
154 days to decisionK001552 · Product code: **LIP** · Microbiology
Source: <https://www.510kdatabase.net/k001552/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorption Assay, Treponema Pallidum (LIP)
Date received	May 18, 2000
Decision date	Oct 19, 2000
Days to decision	154 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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