

K961317 SYPHILIS IGM HUMAN SERUM CONTROLSJun 24, 1996
80 days to decisionK961317 · Product code: **LIP** · Microbiology
Source: <https://www.510kdatabase.net/k961317/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorption Assay, Treponema Pallidum (LIP)
Date received	Apr 5, 1996
Decision date	Jun 24, 1996
Days to decision	80 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Pyramid Biological Corp.
Location	Van Nuys, CA, US
Contact	JEANETTE R PORETTA
510(k) history	12 submissions · 12 cleared · 1993-1997

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