

K970931 COPALIS TORC TOTAL ANTIBODY ASSAYApr 24, 1997
48 days to decisionK970931 · Product code: **LQN** · Microbiology
Source: <https://www.510kdatabase.net/k970931/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Agglutination Assay, Rubella (LQN)
Date received	Mar 7, 1997
Decision date	Apr 24, 1997
Days to decision	48 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sienna Biotech, Inc.
Location	Bethesda, MD, US
Contact	JUDITH J SMITH
510(k) history	3 submissions · 3 cleared · 1996-1997

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