

**K970100 TECH SIMPLE SYPHILIS POSITIVE SERUM CONTROL
MONITOR ONTRAK SYPHILIS POSITIVE SERUM CONTROL**Mar 10, 1997
59 days to decisionK970100 · Product code: **MJX** · Microbiology
Source: <https://www.510kdatabase.net/k970100/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Serological, Positive Control (MJX)
Date received	Jan 10, 1997
Decision date	Mar 10, 1997
Days to decision	59 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Simplicity Diagnostics, Inc.
Location	Hatboro, PA, US
Contact	JEFFREY FLEISHMAN
510(k) history	5 submissions · 5 cleared · 1992-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k970100/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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