

**K993782 SIMPLEX CONDOMS, LATEX CONDOMS-WITH
SPERMICIDAL LUBRICANT (NONOXYNOL-9)**Feb 2, 2000
86 days to decisionK993782 · Product code: **HIS** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k993782/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Condom (HIS)
Date received	Nov 8, 1999
Decision date	Feb 2, 2000
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	P.T. Vonix Latexindo Condom (Rubber) Mfg.
Location	Framingham, MA, US
Contact	VIJAY MAHAL
510(k) history	3 submissions · 3 cleared · 2000-2000

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k993782/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026