

K990925 MALE NATURAL RUBBER LATEX CONDOM (WITH LUBRICATION)Jun 17, 1999
90 days to decisionK990925 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k990925/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Condom (HIS)
Date received	Mar 19, 1999
Decision date	Jun 17, 1999
Days to decision	90 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Hardcover Products, Inc.
Location	Concord, Ontario, CA
Contact	GERRY GLAZER
510(k) history	2 submissions · 2 cleared · 1999-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k990925/> 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