

K943064 KIMONO (CONDOMS)Sep 22, 1995
476 days to decisionK943064 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k943064/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Jun 3, 1994
Decision date	Sep 22, 1995
Days to decision	476 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Mayer Laboratories
Location	Oakland, CA, US
Contact	DAVID P MAYER
510(k) history	16 submissions · 16 cleared · 1987-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k943064/> 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 May 20, 2026