

K910550 CONDOMS/SAXON, GOLD CIRCLE COIN, EMBRACE & RAINBOWJun 3, 1991
116 days to decisionK910550 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k910550/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Feb 7, 1991
Decision date	Jun 3, 1991
Days to decision	116 days
Third-party review	No

APPLICANT

Company	Safetex Corp.
Location	Colonial Heights, VA, US
Contact	RONALD L DAVIS
510(k) history	7 submissions · 7 cleared · 1990-1993

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k910550/> 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 30, 2026