FDA 510(k) Premarket Notification

K896339 MODIFIED LABELING ON OKAMOTO HARMONY CONDOM

CLEARED

Jan 10, 1990
68 days to decision

K896339 · Product code: **HIS** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k896339/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Nov 3, 1989
Decision date	Jan 10, 1990
Days to decision	68 days
Third-party review	No

APPLICANT

Company	**Okamoto USA, Inc.**
Location	Stratford, CT, US
Contact	JEFFREY N GIBBS
510(k) history	14 submissions · 14 cleared · 1987-2025

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k896339/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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