FDA 510(k) Premarket Notification

K875111 RUBBER CONTRACEPTIVE, LATEX CONDOMS

CLEARED

Feb 26, 1988
74 days to decision

K875111 · Product code: **HIS** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k875111/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Dec 14, 1987
Decision date	Feb 26, 1988
Days to decision	74 days
Third-party review	No

APPLICANT

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