FDA 510(k) Premarket Notification

CLEARED

K203541 Okamoto 002 Lubricated Polyurethane Male Condom

Feb 25, 2022
449 days to decision

K203541 · Product code: **MOL** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k203541/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom, Synthetic (MOL)
Date received	Dec 3, 2020
Decision date	Feb 25, 2022
Days to decision	449 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Hyman, Phelps & McNamara, P.C.**
Contact	Jeff N. Gibbs

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov