FDA 510(k) Premarket Notification

K252622 Male Latex Condom HA

CLEARED

May 4, 2026
258 days to decision

K252622 · Product code: **HIS** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k252622/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Condom (HIS)
Date received	Aug 19, 2025
Decision date	May 4, 2026
Days to decision	258 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Okamoto USA, Inc.**
Location	Stratford, CT, US
Contact	Kenji Komatsu
510(k) history	15 submissions · 15 cleared · 1987-2026

REGULATORY CONSULTANT

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

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