

K243584 0.04 ZERO ZERO FOUR Male Latex CondomFeb 18, 2025
90 days to decisionK243584 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k243584/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Condom (HIS)
Date received	Nov 20, 2024
Decision date	Feb 18, 2025
Days to decision	90 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	14 submissions · 14 cleared · 1987-2025

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](https://accessdata.fda.gov)

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