

K192669 Extremely Thin 003, ZERO ZERO THREEJul 24, 2020
303 days to decisionK192669 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k192669/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Condom (HIS)
Date received	Sep 25, 2019
Decision date	Jul 24, 2020
Days to decision	303 days
Third-party review	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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192669/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026