FDA 510(k) Premarket Notification

K192669 Extremely Thin 003, ZERO ZERO THREE

CLEARED

Jul 24, 2020
303 days to decision

K192669 · Product code: **HIS** · Obstetrics & Gynecology
Source: 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