

K212928 LoralsApr 22, 2022
220 days to decisionK212928 · Product code: **MSC** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k212928/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Barrier, Std, Oral Sex (MSC)
Date received	Sep 14, 2021
Decision date	Apr 22, 2022
Days to decision	220 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Brazen Goods Inc. Db a Lorals
Location	Los Angeles, CA, US
Contact	Melanie Cristol
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Acknowledge Regulatory Strategies, LLC
Contact	Erin Gontang

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

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