

**K212037 SancDam Latex Oral Dam**Mar 28, 2022  
271 days to decisionK212037 · Product code: **MSC** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k212037/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Barrier, Std, Oral Sex (MSC)
Date received	Jun 30, 2021
Decision date	Mar 28, 2022
Days to decision	271 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Sanctuary Health Sdn. Bhd.</b>
Location	Chemor, MY
Contact	Sumethi Selavaraju
510(k) history	1 submissions · 1 cleared · 2022-2022

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212037/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026