

K203727 Harmony Latex Dam, Harmony Non-Latex DamAug 5, 2021
227 days to decisionK203727 · Product code: **MSC** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k203727/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Barrier, Std, Oral Sex (MSC) |
| Date received | Dec 21, 2020 |
| Decision date | Aug 5, 2021 |
| Days to decision | 227 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Pamco Distributing, Inc. |
| Location | Kitchener, CA |
| Contact | Annette Maclean |
| 510(k) history | 1 submissions · 1 cleared · 2021-2021 |

REGULATORY CONSULTANT

| | |
|-----------------|--------------------------------------|
| Consulting firm | Ironstone Product Development |
| Contact | Catriona Boyd |

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203727/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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