

K221137 Play and Joy Water-Based LubricantJul 11, 2023
448 days to decisionK221137 · Product code: **NUC** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k221137/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lubricant, Personal (NUC)
Date received	Apr 19, 2022
Decision date	Jul 11, 2023
Days to decision	448 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Innovemed Bio-Tech Co., Ltd.
Location	Taipei City, TW
Contact	Linda Li
510(k) history	2 submissions · 2 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Manton Business and Technology Services
Contact	Charles Shen

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/k221137/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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