

K220226 X-Y Lubricating JellyMar 28, 2023
425 days to decisionK220226 · Product code: **NUC** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k220226/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lubricant, Personal (NUC)
Date received	Jan 27, 2022
Decision date	Mar 28, 2023
Days to decision	425 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	R&R Medical Corporation, Ltd.
Location	New Taipei City, TW
Contact	Wilson Chang
510(k) history	2 submissions · 2 cleared · 2022-2023

REGULATORY CONSULTANT

Consulting firm	Voler Biotech Consulting CO., Ltd.
Contact	Kao Chih Hao

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

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