

K212104 Water-soluble Personal LubricantNov 18, 2021
135 days to decisionK212104 · Product code: **NUC** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k212104/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lubricant, Personal (NUC)
Date received	Jul 6, 2021
Decision date	Nov 18, 2021
Days to decision	135 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Foshan Pingchuang Medical Technology Co., Ltd.
Location	Foshan, CN
Contact	Huang Zhiyue
510(k) history	2 submissions · 2 cleared · 2021-2025

REGULATORY CONSULTANT

Consulting firm	Shenzhen Joyantech Consulting Co., Ltd.
Contact	Joyce Yang

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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