

K243107 Water Solubility Human Body LubricantMay 9, 2025
221 days to decisionK243107 · Product code: **NUC** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k243107/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lubricant, Personal (NUC)
Date received	Sep 30, 2024
Decision date	May 9, 2025
Days to decision	221 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dongguan Yanxuan Biotechnology Co., Ltd.
Location	Dongguang, CN
Contact	Wang Long
510(k) history	1 submissions · 1 cleared · 2025-2025

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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