

K182100 Smile Makers Personal LubricantApr 25, 2019
265 days to decisionK182100 · Product code: **NUC** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k182100/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lubricant, Personal (NUC)
Date received	Aug 3, 2018
Decision date	Apr 25, 2019
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Lfbeauty (Thailand) Limited
Location	Lamlukka, TH
Contact	Apasara Kaewlor
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Pharmeng Technology
Contact	Shelley 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/k182100/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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