FDA 510(k) Premarket Notification

K190752 Satisfaite

CLEARED

Dec 13, 2019
263 days to decision

K190752 · Product code: **NUC** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k190752/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lubricant, Personal (NUC)
Date received	Mar 25, 2019
Decision date	Dec 13, 2019
Days to decision	263 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Femmepharma Consumer Healthcare, LLC**
Location	Wayne, PA, US
Contact	Gerianne DiPiano
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	**Emergo by UL**
Contact	Stuart R. Goldman

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