

K162319 BabyDance Fertility LubricantApr 28, 2017
252 days to decisionK162319 · Product code: **PEB** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k162319/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lubricant, Personal, Gamete, Fertilization, And Embryo Compatible (PEB)
Date received	Aug 19, 2016
Decision date	Apr 28, 2017
Days to decision	252 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fairhaven Health, LLC
Location	Bellingham, WA, US
Contact	Suzanne Munson
510(k) history	2 submissions · 2 cleared · 2017-2019

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