

K193450 Pre-Seed™ Fertility LubricantJul 23, 2020
223 days to decisionK193450 · Product code: **PEB** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k193450/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lubricant, Personal, Gamete, Fertilization, And Embryo Compatible (PEB)
Date received	Dec 13, 2019
Decision date	Jul 23, 2020
Days to decision	223 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Church & Dwight Co., Inc.
Location	Princeton, NJ, US
Contact	Joelle Reinson
510(k) history	29 submissions · 29 cleared · 2006-2025

Church & Dwight Co., Inc. is an American consumer goods company headquartered in Princeton, New Jersey. Founded in 1847, the company manufactures personal care, household, and specialty products under brands including Arm & Hammer, Trojan, OxiClean, and First Response. Church & Dwight has received FDA 510(k) clearances from total submissions since 2006. The company's regulatory focus centers on Obstetrics & Gynecology devices, which represent 86% of submissions. The latest clearance was issued in 2025, reflecting continued regulatory activity. The company's cleared device...
