

K191462 Proov TestFeb 27, 2020
269 days to decisionK191462 · Product code: **QKE** · Chemistry
Source: <https://www.510kdatabase.net/k191462/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay, Pregnanediol Glucuronide, Over The Counter (QKE)
Date received	Jun 3, 2019
Decision date	Feb 27, 2020
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Mfb Fertility, Inc.
Location	Erie, CO, US
Contact	Amy Beckley
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Medical Device Academy, Inc.
Contact	Mary Vater

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/k191462/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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