

**K231645 PherDal® At-Home Insemination Kit**Dec 14, 2023  
192 days to decisionK231645 · Product code: **QYZ** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k231645/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	At Home Intravaginal Insemination System (QYZ)
Date received	Jun 5, 2023
Decision date	Dec 14, 2023
Days to decision	192 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Pherdal Fertility Science, Inc.</b>
Location	Dixon, IL, US
Contact	Dr. Jennifer Hintzsche Westphal
510(k) history	1 submissions · 1 cleared · 2023-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Iuvo Consulting, LLC</b>
Contact	Dr. Rhonda Alexander

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

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