December 14, 2023

PherDal Fertility Science, Inc.
℅ Rhonda Alexander
Sr. Consultant, Regulatory Strategy
IUVO Consulting, LLC
P.O. Box 56436
Virginia Beach, VA 23456

Re: K231645
Trade/Device Name: PherDal® At-Home Insemination Kit
Regulation Number: 21 CFR§ 884.6110
Regulation Name: Assisted Reproduction Catheters
Regulatory Class: II
Product Code: QYZ
Dated: November 13, 2023
Received: November 13, 2023

Dear Rhonda Alexander:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael T. Bailey -S

For
Monica D. Garcia, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K231645

Device Name
PherDal® At-Home Insemination Kit

Indications for Use *(Describe)*
The PherDal® At-Home Insemination Kit is indicated for over-the-counter home use, by individuals who have been unable to conceive through intercourse or have chosen not to conceive through intercourse, for semen collection and the delivery of semen to the vaginal canal. The PherDal® At-Home Insemination Kit should be used during the ovulatory phase of the menstrual cycle.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary
K231645

Date Prepared: December 11, 2023

I. SUBMITTER

PherDal Fertility Science, Inc.
405 W 2nd St, Unit 1141
Dixon, IL 61021 USA

Contact Person:

Jennifer D. Westphal, Ph.D.
CEO and Founder
405 W 2nd St, Unit 1141
Dixon, IL 61021 USA
Phone: (872) 216-8330
Email: Support@PherDal.com

II. SUBMISSION CORRESPONDENT

Rhonda Alexander, DSL
IUVO Consulting, LLC
PO Box 56436
Virginia Beach, VA 23456
United States

Phone: (757) 582-4337 (direct)
(202) 792-8344 (office)
E-mail: ralexander@iuvoconsulting.com

III. DEVICE

Name of Device:	PherDal® At-Home Insemination Kit
Common Name:	At Home Intravaginal Insemination System
Regulation Number:	21 CFR 884.6110
Classification Name:	Assisted Reproduction Catheters
Regulatory Class:	Class II
Product Code:	QYZ (At Home Intravaginal Insemination System)

IV. PREDICATE DEVICE

Insemi-Cath® Intrauterine Insemination Catheter (K172321)

This predicate device has not been subject to a design-related recall.

V. DEVICE DESCRIPTION

The PherDal® At-Home Insemination Kit is a sterile, over-the-counter (OTC) medical device intended for intravaginal insemination (IVI) at home. It consists of three sets of sterile, single-use, plastic syringes and semen collection cups, and Instructions for Use. The collection cup is used to hold and contain the sperm and work in

conjunction with the syringe when it is time to transfer the sperm into the syringe. The syringe is used to withdraw the semen from the collection cup and deploy the semen intravaginally.

VI. INDICATIONS FOR USE

The PherDal® At-Home Insemination Kit is indicated for over-the-counter home use, by individuals who have been unable to conceive through intercourse or have chosen not to conceive through intercourse, for semen collection and the delivery of semen to the vaginal canal. The PherDal® At-Home Insemination Kit should be used during the ovulatory phase of the menstrual cycle.

VII. COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Comparison Item	**Subject Device K231645**	**Predicate Device K172321**	**Comparison**
Indications for Use	The PherDal® At-Home Insemination Kit is indicated for over-the-counter home use, by individuals who have been unable to conceive through intercourse or have chosen not to conceive through intercourse, for semen collection and the delivery of semen to the vaginal canal. The PherDal® At-Home Insemination Kit should be used during the ovulatory phase of the menstrual cycle.	Intrauterine Insemination Catheters are used for the introduction of washed spermatozoa into the uterine cavity.	Different
Intended Environment for Use	Over-the-counter use	Prescription use	Different
Insemination Procedure	Intravaginal insemination	Intrauterine insemination	Different
Device Components/Materials	Collection Cup: Polystyrene Plunger: Polycarbonate, ABS Blend, Thermoplastic Elastomer Syringe Body: Polystyrene	Insemi-Cath®: Nylon, Silicone	Different
Sterility	Sterile	Sterile	Same
Single Use	Yes	Yes	Same

The subject and predicate devices have differences in their indications for use statements, as the PherDal At-Home Insemination Kit is for delivery of semen to the vagina, while the predicate device is for delivery of washed spermatozoa to the uterine cavity. In addition, the PherDal® At-Home Insemination Kit is for OTC home use, while the predicate is a prescription use device for use in a clinical setting. The differences between the indications for use for the two devices do not represent a new intended use as both devices are intended to deliver sperm to the female reproductive tract as an aid to conception.

The subject and predicate devices have differences in technological characteristics, including device components, type of procedure, environment of use, materials, and sterility, as shown above. These differences do not raise different questions of safety or effectiveness.

VIII. NON-CLINICAL PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

Biocompatibility testing was performed in accordance with the 2020 FDA guidance document, Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process," as follows:

- Cytotoxicity per ISO 10993-5:2009
- Sensitization per ISO 10993-10:2010
- Vaginal irritation per ISO 10993-23:2021

The results of testing demonstrated that the subject device is non-cytotoxic, non-irritating, and non-sensitizing.

Sterilization Validation

The subject devices are gamma irradiation sterilized. The sterilization process and validation methods were done in accordance with ISO 11137-1:2006 and ISO 11137-2:2013, and the 2016 FDA guidance document, Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile. The sterilization assurance level of the subject device is 10^{-6}.

Transport Testing

Simulated transport testing was conducted to demonstrate the ability of device packaging to withstand the rigors of shipping per the 2016 FDA guidance document, Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile. Testing was performed in accordance with ASTM D4169-22.

Shelf Life

A shelf-life study was conducted on test articles that were newly manufactured and aged under accelerated conditions to the end of the five-year shelf-life, per ASTM F1980-21. Specifications assessed in support of the device shelf-life include the following, which are further described below:

- Packaging Integrity Testing
- Functional Testing
- Human Sperm Survival Assay (HSSA)

Packaging Integrity Testing

Verification of the ability of device packaging to maintain a sterile barrier over the five-year shelf-life of the device was assessed using the following methods:.

- Seal strength testing per ASTM F88/F88M-15
- Seal integrity testing per ASTM F1886/F1886M-16
- Seal width test per ASTM F2203-13 (Reapproved 2022)
- Bubble leak testing per ASTM F2096-11 (Reapproved 2019)

Functional Testing

Functional testing on the PherDal syringe and collection cup was conducted on newly manufactured devices and devices at the end of shelf-life.

The tests for the syringe, developed based on ISO 7886-1:2017, include:

- Visual inspection (clause 6.1)
- Dimensional inspection (clauses 10.1 and 11.1)
- Freedom from liquid leakage past plunger stopper (clause 13.2)

- Force to operate the piston (clause 13.3),
- Fit of plunger stopper/plunger in barrel (clause 13.4)

The tests for the collection cup include:

- Visual inspection
- Dimensional inspection

Human Sperm Survival Assay (HSSA)

HSSA was conducted on the syringe and collection cup to demonstrate that the syringe and cup materials are not sperm-toxic. The HSSA was conducted on newly manufactured devices and devices at the end of shelf-life.

Syringes and collection cups were shown to meet the HSSA acceptance specification (≥80% of control motility at 24 hours) at all time points assessed.

IX. CLINICAL PERFORMANCE DATA

Self-Selection Study

A self-selection study for the PherDal® At-Home Insemination Kit assessed whether potential users could accurately determine if they should use the product or not based on the box label. The study consisted of eighty-seven (87) biological female participants: forty-seven (47) contraindicated female participants and forty (40) non-contraindicated female participants. All participants varied in age (18-44), ethnicity, and English health literacy level [as determined by the Rapid Estimate of Adult Literacy in Medicine (REALM) test]. The participants were representative of the U.S. demographic and the intended use population. Additionally, all participants reported that they were attempting to conceive and had varying degree of comfort/experience in using and inserting devices into the vagina. The study results showed that 98.9% (86 of 87) of all study participants were able to successfully determine whether the PherDal® At-Home Insemination Kit was intended for them or not based on the information on the labeling. Also, those with low health literacy had 97.0% (33/34) success in correctly identifying if the product was intended for them or not.

In summary participants in the self-selection study were able to identify the following information on the box label:

- Who the kit is indicated/intended for
- Whether it is acceptable for them to use the product (and why or why not)
- Who should not use the kit
- When the kit should not be used (i.e., warnings, precautions)
- What the product acknowledges that it does not do

Labeling Comprehension Study

A labeling comprehension study assessed whether potential users could adequately understand how to successfully use the PherDal® At-Home Insemination Kit based on the box label and the Instructions for Use. The target threshold was for greater than or equal to 90% of study participants to be able to understand the product label as determined by a comprehensive set of knowledge questions (65 total questions). The study enrolled 164 biological female participants. All participants varied in age (>18 years old), gender, ethnicity, English health literacy level [as determined by the Rapid Estimate of Adult Literacy in Medicine (REALM) test], and had varying degree of comfort/experience in using and inserting devices into the vagina. The participants were representative of the U.S. demographic and the intended use population.

Participants were asked to review the box label and Instructions for Use and advised in a self-directed manner to answer the series of 65 questions about the information in the labeling that assessed the following:

- Understanding the intended use of the device

- Understanding when and how to use the device
- Understanding Warnings and Precautions
- Understanding how to store the device
- Understanding how long the semen sample can be used after collection
- Understanding what not to do after filling the syringe until the syringe is fully inserted in the vagina
- Understanding what the female recipient should do after the insemination procedure
- Understanding not to use the device after the expiration date or if the packaging is damaged
- Understanding that the device does not guarantee pregnancy or treat infertility
- Understanding how long to use the device without successful results before contacting a physician

Results: All questions were answered correctly by at least 90% of study participants (range 95-100%). Additionally, at least 90% participants with low health literacy were able to correctly answer the label comprehension questions as well (range 91-100%). None of the participants stated difficulty in understanding the answers to any of the questions. Therefore, the target threshold of at least 90% success of the label comprehension study for the PherDal® At-Home Insemination Kit was met.

X. CONCLUSIONS

The results of the performance testing supports a determination of substantial equivalence of the subject device to the predicate device, OTC use of the device, and do not raise any new questions of the safety or effectiveness.