JUL 2 2 2014

Applicant:	Auxogyn, Inc. 1490 O'Brien Drive, Suite A Menlo Park, CA 94025
Contact Person:	Julia S. Anastas Director, Regulatory Affairs Phone: 650.763.3875 Fax: 650.763.3875 E-mail: janastas@auxogyn.com
Date Summary Prepared:	July 14, 2014
Device Common Name:	IVF Culture Dish
Device Classification:	Class II
Regulation Number:	21 CFR 884.6160
Classification Name:	Assisted Reproduction Labware
Product Code:	MQK
Device Proprietary Name	Eeva™ Dish
Predicate Device:	Eeva™ Petri Dish
Predicate Device Manufacturer:	Auxogyn, Inc. 1490 O'Brien Drive Menlo Park, CA 94025
Predicate Device Common Name:	IVF Culture Dish
Predicate Device Premarket Notification Number:	K103028
Predicate Device Classification:	Class II
Predicate Device Regulation Number:	21 CFR 884.6160
Classification Name:	Assisted Reproduction Labware
Product Code:	MQK
Device Description:	The Eeva Dish is a round dish with an outer diameter of 38 mm; the inner diameter of the dish is 35mm. The dish is provided with a lid. The interior of the dish contains a large central ring approximately 10mm in diameter, which contains 12 smaller, round microwells, each intended to hold a single human oocyte or embryo. The device allows for the segregation of embryos while they are immersed in the same drop of culture media The microwells are 350 microns in diameter and 134 microns deep, which creates sufficient room for handling of human oocytes and embryos with a pipette. The center ring has a tapered wall to stabilize and minimize embryo movement in the microwells. The dish also contains three smaller outer rings, approximately 8mm in diameter each, that are intended to hold media drops for rinsing oocytes or embryos. The center and three outer rings can each hold 100µL of media.

The dish is constructed of virgin polystyrene and is non-pyrogenic and non-embryotoxic. The dish is single use only and is packaged with 3 units per sterile pouch, 12 pouches per corrugated cardboard shipping carton.

Indications for Use: The Eeva™ Dish is intended to be used to hold human oocytes and embryos during handling and culture.

Technological Characteristics and Comparison to Predicate Device: The dish with 12 microwells is substantially equivalent in indications for use, intended use, and materials and design to the predicate device, the dish with 16 or 25 microwells, cleared as the Eeva™ Petri Dish. A comparison of the subject and predicate devices is presented in the table below.

Characteristic	New Device (K141663) Eeva Dish, 12-Microwell configuration	Predicate Device (K103028) Eeva Petri Dish, 16- and 25-Microwell configurations
Indications for Use	The Eeva™ Dish is intended to hold human oocytes and embryos during handling and culture.	Same
Principles of Operation / Conditions of Use	Microwell tissue culture dish for use in IVF procedures performed by qualified professionals. The dish is a restricted device.	Same
Dish and Lid Materials	100% virgin polystyrene	Same
Shelf-life	6-months	Same
Sterilization	Gamma irradiation to an SAL of 10^{-6}	Same
Packaging	Dish is packaged as 3 dish units in a sterile, nylon, film-to-film pouch (single-use only)	Same
Pyrogenicity Testing	Non-pyrogenic as tested by Limulus Amoebocyte Lysate (LAL) testing (≤ 20 EU/Device)	Same
Embryotoxicity Testing	Non-embryotoxic as tested by 1-Cell Mouse Embryo Assay (MEA), with ≥ 80% of embryos developing to expanded blastocyst stage within 96 hours.	Same

Characteristic	New Device (K141663) Eeva Dish, 12-Microwell configuration	Predicate Device (K103028) Eeva Petri Dish, 16- and 25-Microwell configurations	
Dish Dimensions			
Dish Inside Diameter (mm)	35	Same	
Dish Outside Diameter (mm)	38	39	39
Dish Height (mm)	11	Same	
Central Ring, Diameter(mm)	10	9	7
Central Ring, Height(mm)	2.5	0.5	0.5
Central Ring Walls	Beveled walls to stabilize embryos in microwells	Straight walls, no bevel	
Central Ring Volume (µL of media)	100	80	50
3 Outer Rings, Diameter (mm)	8	7	7
3 Outer Rings, Height (mm)	2.5	0.5	0.5
3 Outer Rings, Volume (µL of media)	100	50	50
Microwell Dimensions			
Number of Microwells (in central ring)	12 microwells	16 microwells	25 microwells
Microwell shape & size (microns)	Circle 350	Square 300 x 300	Square 250 x 250
Microwell depth (microns)	134	150	100

Dish and microwell dimensional differences between the new device and the predicate are minor. The modified dish and microwell dimensions are intended to provide flexibility for the user and aid in device usability. The minor differences in dimensions do not represent a new technology raising new types of safety or effectiveness questions.

Summary of Non-clinical Supporting Data:	Non-clinical testing was conducted on the Eeva Dish with 12 microwells to support a determination of substantial equivalence to the predicate devices. Testing included: Pyrogenicity Testing Embryotoxicity Testing Packaging Integrity Shipping Validation Sterilization Validation Shelf Life Verification Lab Equipment Compatibility Verification Usability Verification
Conclusion:	When compared to the predicate device, the Eeva Dish has the same indication for use and intended use. In addition, the Eeva Dish does not incorporate any significant changes in method of operation, material, or design that would result in a new technology raising new types of safety or effectiveness questions. Therefore, the Eeva Dish, 12-microwell configuration is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 22, 2014

Auxogyn, Inc.
Julia Anastas
Director, Regulatory Affairs
1409 O'Brien Drive, Suite A
Menlo Park, CA 94025

Re: K141663
Trade/Device Name: Eeva™ Dish
Regulation Number: 21 CFR§ 884.6160
Regulation Name: Assisted Reproduction Labware
Regulatory Class: Class II
Product Code: MQK
Dated: June 19, 2014
Received: June 23, 2014

Dear Julia Anastas,

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 (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. 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.

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141663

Device Name
Eeva™ Dish

Indications for Use *(Describe)*
The Eeva™ Dish is intended to be used to hold human oocytes and embryos during handling and culture.

Benjamin R. Fisher -S
2014.07.22 16:27:00 -04'00'

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."