Food and Drug Administration
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March 26, 2015

Auxogyn, Inc.
c/o Ms. Cindy Domecus, R.A.C
Principal, Domecus Consulting Services LLC
1171 Barroilhet Drive
Hillsborough, CA 94010

Re: K120427/DEN120015
        Eeva® System
        Evaluation of Automatic Class III Designation – *De Novo* Request
        Regulation Number: 21 CFR 884.6195
        Regulation Name: Assisted Reproduction Embryo Image Assessment System
        Regulatory Classification: Class II
        Product Code: PBH
        Dated: August 23, 2012
        Received: August 24, 2012

Dear Ms. Domecus:

This letter corrects our classification order of June 6, 2014.

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration
(FDA) has completed its review of your *de novo* request for classification of the Eeva® System,
a prescription device under 21 CFR Part 801.109 that is indicated to provide adjunctive
information on events occurring during the first two days of development that may predict
further development to the blastocyst stage on Day 5 of development. This adjunctive
information aids in the selection of embryo(s) for transfer on Day 3 when, following
morphological assessment on Day 3, there are multiple embryos deemed suitable for transfer or
freezing. FDA concludes that this device should be classified into class II. This order, therefore,
classifies the Eeva® System, and substantially equivalent devices of this generic type, into class
II under the generic name, Assisted Reproduction Embryo Image Assessment System.

FDA identifies this generic type of device as:

> **Assisted Reproduction Embryo Image Assessment System**: An assisted reproduction
> embryo image assessment system is a prescription device that is designed to obtain and
> analyze light microscopy images of developing embryos. This device provides
> information to aid in the selection of embryo(s) for transfer when there are multiple
> embryos deemed suitable for transfer or freezing.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607
of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This
new law provides two options for *de novo* classification. First, any person who receives a "not

substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on August 3, 2012 automatically classifying the Eeva® System in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, nor which was subsequently reclassified into class I or class II. On August 24, 2012, FDA received your *de novo* requesting classification of the Eeva® System into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Eeva® System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the *de novo* request, FDA has determined that the Eeva® System indicated to provide adjunctive information on events occurring during the first two days of development that may predict further development to the blastocyst stage on Day 5 of development. This adjunctive information aids in the selection of embryo(s) for transfer on Day 3 when, following morphological assessment on Day 3, there are multiple embryos deemed suitable for transfer or freezing, can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type.   The identified risks and mitigation measures associated with the device type are summarized in Table 1.

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk	Mitigation Measures
Damage or Destruction of the Embryo	Non-Clinical Performance Testing Software Verification, Validation & Hazard Analysis Clinical Testing Electromagnetic Compatibility Testing Electrical Safety Testing Labeling Training
Infection (Contamination of Device, Labware, and Incubator)	Cleaning and Disinfection Validation Labeling Training
Incorrect Embryo Development Prediction	Non-Clinical Performance Testing Software Verification, Validation & Hazard Analysis Clinical Testing Labeling

	Training
Electromagnetic Interference/Electrical Safety Issues	Electromagnetic Compatibility Testing Electrical Safety Testing Labeling
User Error	Labeling Training

In combination with the general controls of the FD&C Act, Assisted Reproduction Embryo Image Assessment Systems are subject to the following special controls:

1. Clinical performance testing must demonstrate a reasonable assurance of the safety and effectiveness of the device to predict embryo development. Classification performance (sensitivity and specificity) and predictive accuracy (Positive Predictive Value and Negative Predictive Value) must be assessed at the subject and embryo levels.

2. Software validation, verification, and hazard analysis must be provided.

3. Non-clinical performance testing data must demonstrate the performance characteristics of the device. Testing must include the following:
    a. Total light exposure and output testing
    b. A safety analysis must be performed based on maximum (worst-case) light exposure to embryos, which also includes the safety of the light wavelength(s) emitted by the device
    c. Simulated-use testing
    d. Mouse Embryo Assay (MEA) testing to assess whether device operation impacts growth and development of mouse embryos to the blastocyst stage
    e. Cleaning and disinfection validation of reusable components
    f. Package integrity and transit testing
    g. Hardware fail-safe validation
    h. Electrical equipment safety and electromagnetic compatibility testing
    i. Prediction algorithm reproducibility

4. Labeling must include the following:
    a. A detailed summary of clinical performance testing, including any adverse events
    b. Specific instructions, warnings, precautions, and training needed for safe use of the device
    c. Appropriate electromagnetic compatibility information
    d. Validated methods and instructions for cleaning and disinfection of reusable components
    e. Information identifying compatible cultureware and explain how they are used with the device

In addition, this is a prescription device and must comply with 21 CFR 801.109. Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type.

FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Assisted Reproduction Embryo Image Assessment System they intend to market prior to marketing the device and receive clearance to market from FDA.

Please be advised that FDA's decision to grant this *de novo* request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD & C 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 FD & C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the *de novo* request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Michael Bailey, Ph.D. at 301-796-6530.

Sincerely yours,

Jonette R. Foy -S

Jonette Foy, Ph.D.
Deputy Director
   for Engineering and Science Review
Office of Device Evaluation
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