



Food and Drug Administration
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February 12, 2015

Pelvalon, Inc.
% Cindy Domecus
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Re: DEN140020
Eclipse System
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 876.5930
Regulation Name: Rectal Control System
Regulatory Classification: Class II
Product Code: PJH
Dated: June 23, 2014
Received: June 25, 2014

Dear Ms. Domecus:

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 Eclipse System, a prescription device under 21 CFR Part 801.109 that is indicated *for the treatment of fecal incontinence in adult women*. FDA concludes that this device should be classified into class II. This order, therefore, classifies the Eclipse System, and substantially equivalent devices of this generic type, into class II under the generic name, Rectal Control System.

FDA identifies this generic type of device as:

Rectal Control System: A rectal control system is a prescription device intended to treat fecal incontinence by controlling the size of the rectal lumen. The device is inserted in the vagina and includes a portion that expands to reduce the rectal lumen to prevent stool leakage and retracts to allow normal passage of stool. The device includes an external regulator to control the state of expansion.

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.

On June 25, 2014, FDA received your *de novo* requesting classification of the Eclipse System into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Eclipse 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 Eclipse System indicated *for the treatment of fecal incontinence in adult women* 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 Method
Vaginal Wall Trauma	<ul style="list-style-type: none"> • Clinical Testing • Labeling
Adverse Tissue Reaction	<ul style="list-style-type: none"> • Biocompatibility Testing
Infection	<ul style="list-style-type: none"> • Non Clinical (bench) Testing • Cleaning and Disinfection Validation • Labeling
Device Malfunction	<ul style="list-style-type: none"> • Non Clinical (bench) Testing • Labeling
Urinary Urgency, Incontinence or Voiding Problems	<ul style="list-style-type: none"> • Clinical Testing • Labeling
Fecal Urgency, or Difficulty in Evacuation	<ul style="list-style-type: none"> • Clinical Testing • Labeling
Discomfort, Pain	<ul style="list-style-type: none"> • Clinical Testing • Labeling
Change in amount, color, or consistency of vaginal discharge	<ul style="list-style-type: none"> • Labeling

In combination with the general controls of the FD&C Act, the Rectal Control System is subject to the following special controls:

1. Clinical testing must document the device acceptance data and the adverse event profile associated with clinical use, and demonstrate that the device performs as intended under anticipated conditions of use.

2. The elements of the device that contact vaginal tissue must be demonstrated to be biocompatible.
3. The cleaning and disinfection instructions for the device must be validated.
4. Non-clinical (bench) testing must demonstrate that the device performs as intended under anticipated conditions of use.
5. Non-clinical (bench) testing must demonstrate that the device does not:
 - a. Enhance the growth of *Staphylococcus aureus*
 - b. Increase production of Toxic Shock Syndrome Toxin -1 by *S. aureus*
 - c. Alter the growth of normal vaginal flora
6. Labeling must include:
 - a. Specific instructions, contraindications, warnings, cautions, limitations, and the clinical training needed for the safe use of the device.
 - b. The intended patient population and the intended use environment.
 - c. Information on how the device is to be fitted, how the device operates, and recommendations on device maintenance.
 - d. A detailed summary of the clinical testing pertinent to the use of the device, including a summary of the device- and procedure-related complications or adverse events related to use of the device, as well as relevant safety and performance information.
7. Patient labeling must be provided and must include:
 - a. Relevant contraindications, warnings, precautions, and adverse events/complications.
 - b. Information on how the device operates and the recommended device maintenance (i.e., care instructions) including cleaning and disinfection.
 - c. Information on the patient population for which there was a favorable benefit/risk assessment.
 - d. The potential risks and benefits associated with the use of 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 Rectal Control System when 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 Purva Pandya at (240) 402-9979.

Sincerely yours,


Jonette R. Foy -S

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