DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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March 26, 2015

Ergon Medical Ltd.
% Barry Pearce
Regulatory Consultant and Official Correspondent
Shotwell & Carr, Inc.
25 Barker Close, Fishbourne, Chichester
West Sussex, PO 18 8BJ
United Kingdom

Re: DEN130047
Prolong™
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 876.5025
Regulation Name: Vibrator for Climax Control of Premature Ejaculation
Regulatory Classification: Class II
Product Code: PIA
Dated: November 21, 2013
Received: November 22, 2013

Dear Mr. Pearce:

This letter corrects our classification order of March 20, 2015.

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 Prolong™, an over-the-counter device under 21 CFR Subpart C that is indicated for *use as part of a climax control program for males who suffer from premature ejaculation. It is designed to increase the time between arousal and ejaculation through the use of the training sessions using the stimulating vibratory effects of the device on the penis as part of the "start-stop" technique. Prolong is intended to be available as an over-the-counter device.* FDA concludes that this device should be classified into class II. This order, therefore, classifies the Prolong™, and substantially equivalent devices of this generic type, into class II under the generic name, Vibrator for Climax Control of Premature Ejaculation.

FDA identifies this generic type of device as:

> **Vibrator for climax control of premature ejaculation:** A vibrator for climax control of premature ejaculation is used for males who suffer from premature ejaculation. It is designed to increase the time between arousal and ejaculation using the stimulating vibratory effects of the device on the penis.

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 November 22, 2013, FDA received your *de novo* requesting classification of the Prolong™ into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Prolong™ 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 Prolong™ indicated for *use as part of a climax control program for males who suffer from premature ejaculation* 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 Measure
Pain or discomfort due to misuse of device	Labeling
Burns	Electrical and Thermal Safety Testing Labeling
Electrical Shock	Electrical Safety Testing Labeling
Adverse skin reactions	Biocompatibility Testing
Patient injury due to device breakage or failure	Mechanical Durability Testing Labeling
Interference with other devices/electrical equipment	Electromagnetic Compatibility Testing Labeling

In combination with the general controls of the FD&C Act, the Vibrator for Climax Control of Premature Ejaculation is subject to the following special controls:

1. The labeling must include specific instructions regarding the proper placement and use of the device.

2. The portions of the device that contact the patient must be demonstrated to be biocompatible.

3. Appropriate analysis/testing must demonstrate electromagnetic compatibility (EMC) safety, electrical safety, and thermal safety of the device.

4. Mechanical safety testing must demonstrate that the device will withstand forces encountered during use.

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 Vibrator for Climax Control of Premature Ejaculation 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 Tuan Nguyen, Ph.D. at (301) 796-5174.

Sincerely yours,

Jonette R. Foy -S

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