DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-002

National Center for Pelvic Pain Research Devices, Incorporated
% David Wise, Ph.D.
Director
12470 Fiori Lane
Sebastopol, California 95472

NOV 2 0 2012

Re: K100934
AHIP Internal Trigger Point Wand
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 890.5670
Regulation Name: Internal therapeutic massager
Regulatory Classification: Class II
Product Code: OSD
Dated: August 17, 2010
Received: August 20, 2010

Dear Dr. Wise:

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 AHIP Internal Trigger Point Wand, a prescription device under 21 CFR Part 801.109 that is indicated to massage irritable, sore trigger points in the pelvic floor musculature to reduce internal pelvic floor trigger point sensitivity and to relieve painful trigger points. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the AHIP Internal Trigger Point Wand, and substantially equivalent devices of this generic type, into class II under the generic name, internal therapeutic massager.

FDA identifies this generic type of device as:

> Internal therapeutic massager. A hand-held internal therapeutic massager device is a prescription device intended for medical purposes to manually provide direct pressure applied to localized areas of pain or tenderness in the myofascial tissue associated with chronic pelvic pain syndromes. The device is inserted rectally or vaginally and provides quantitative feedback to the user of the applied force to the target tissue.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the FD&C Act), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976 (the amendments)), generally referred to as postamendments devices, are classified automatically by statute into class

III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and Part 807 of the FDA regulations (21 CFR 807).

Section 513(f)(2) of the FD&C Act, also referred to as *de novo* classification or Evaluation of Automatic Class III designation, 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 July 27, 2010 automatically classifying the AHIP Internal Trigger Point Wand 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 17, 2010, FDA received your *de novo* request for classification of the AHIP Internal Trigger Point Wand into class II. The *de novo* request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the AHIP Internal Trigger Point Wand 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 AHIP Internal Trigger Point Wand indicated to massage irritable, sore trigger points in the pelvic floor musculature to reduce internal pelvic floor trigger point sensitivity and to relieve painful trigger points 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 potential risks to health and mitigations associated with the device type are summarized in Table 1.

Table 1 - Risks to Health and Mitigations

Identified Risks	Mitigation Measure
Adverse Tissue Reaction	Biocompatibility testing Labeling
Tissue bruising, abrasion or tearing	Performance testing Labeling
Microbial contamination from reusable components	Labeling
Vaginal/rectal cross-contamination	Labeling
Overstretching/weakness of the anal sphincter and vagina	Performance testing Labeling
Mechanical failure during use	Performance testing
User Error	Labeling
Electrical Hazards	Electrical safety testing Labeling
Electromagnetic Incompatibility	Electromagnetic compatibility testing Labeling
Software Failure	Software testing

In addition to the general controls of the FD&C Act, the internal therapeutic massager is subject to the following special controls: (1) The labeling must include adequate directions for use, including prescribing information, to ensure safe and effective use by the patient; (2) Appropriate analysis/testing must validate electromagnetic compatibility (EMC), electrical safety and mechanical safety; (3) Non-clinical performance testing must demonstrate a reasonable assurance of safety and effectiveness, including mechanical durability and accurate feedback mechanism; (4) Appropriate software verification, validation, and hazard analysis must be performed; and (5) All elements of the device that may contact the patient must be demonstrated to be biocompatible. 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 not necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device type is exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type need not submit a premarket notification containing information on the internal therapeutic massager they intend to market prior to marketing the device and receive clearance to market from FDA subject to the limitations on exemptions in 21 CFR 890.9.

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 Ms. Katherine Kim at 301-796-6900.

Sincerely yours,

Jonette Foy, Ph.D.
Deputy Director
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration