



Food and Drug Administration
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Silver Spring, MD 20993-0002

Mary M. Sorg
P.J. Sleeper's
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Waterford, PA 16441

December 18, 2013

Re: K102707
Restiffic™ Restless Leg Relaxer Foot Wrap
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 890.5760
Regulation Name: Nonpowered lower extremity pressure wrap
Regulatory Classification: Class I
Product Code: OTX
Dated: January 23, 2011
Received: January 27, 2011

Dear Ms. Sorg:

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 Restiffic Restless Leg Relaxer Foot Wrap, a prescription device under 21 CFR Part 801.109 that is intended to reduce symptoms of moderate to severe primary Restless Leg Syndrome (RLS) in adults and used during periods of rest or relaxation, when symptoms of RLS occur. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class I. This order, therefore, classifies the Restiffic Restless Leg Relaxer Foot Wrap, and substantially equivalent devices of this generic type, into class I under the generic name, Nonpowered lower extremity pressure wrap.

FDA identifies this generic type of device as:

Nonpowered lower extremity pressure wrap. A nonpowered lower extremity pressure wrap is a prescription device that applies mechanical pressure by wrapping around the lower extremity, such as the leg or foot, and is intended for primary Restless Leg Syndrome (RLS).

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 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 January 7, 2011, automatically classifying the Restiffic Restless Leg Relaxer Foot Wrap 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 January 23, 2011, FDA received your *de novo* requesting classification of the Restiffic Restless Leg Relaxer Foot Wrap into class I. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Restiffic Restless Leg Relaxer Foot Wrap 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 Restiffic Restless Leg Relaxer Foot Wrap intended to reduce symptoms of moderate to severe primary Restless Leg Syndrome (RLS) in adults and used during periods of rest or relaxation, when symptoms of RLS occur can be classified in class I. FDA believes that class I (general) controls provide reasonable assurance of the safety and effectiveness of the device type. In addition, this is a prescription device and must comply with 21 CFR 801.109. The nonpowered lower extremity pressure wrap is subject to the general controls of the FD&C Act. Section 510(l) of the FD&C Act (21 U.S.C. 360(l)) provides that a class I device is not subject to the premarket notification requirements under section 510(k) of the FD&C Act unless the device is of substantial importance in preventing impairment of human health or presents a potential unreasonable risk of illness or injury. FDA has determined that the device does not meet these criteria and, therefore, premarket notification is not required for the device. Thus, persons who intend to market this device need not submit a premarket notification containing information on the nonpowered lower extremity pressure wrap they intend to market prior to marketing the device 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.

If you have any questions concerning this classification order, please contact Michael Hoffmann at 301-796-6610.

Sincerely yours,

Jonette R. Foy -S

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