



Food and Drug Administration
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February 26, 2016

Natures Pillows, Inc.
c/o Thomas C. Knott
Benjamin L. England and Associates, LLC
810 Landmark Drive, Suite 126
Glen Burnie, MD 21061

Re: K151476

Trade/Device Name: Beactive® Brace
Regulation Number: 21 CFR 890.3475
Regulation Name: Limb Orthosis
Regulatory Class: Class I
Product Code: PMV
Dated: 01/20/2016
Received: 01/21/2016

Dear Mr. Knott,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 80; 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 Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Michael J. Hoffmann -A

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151476

Device Name

Beactive Brace

Indications for Use (Describe)

The Beactive Brace is applied to the to the upper calf just below the knee such that the pressure pad presses against the soleus muscle located just to the outside of the back of the knee for the purpose of temporarily reducing lower back pain that radiates down the leg associated with normal household or work activities.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary K151476 (per 21 CFR 807.92)

I. SUBMITTER

Submitted By: Benjamin L. England And Associates, LLC
Address: 810 Landmark Drive Suite 126
Glen Burnie, MD 21061
Phone: (410) 220-2800
Fax: (443) 583-1464
E-mail: tcknott@fdaimports.com
Contact: Thomas C. Knott, Senior Regulatory Consultant

Date Prepared: February 26, 2016

II. SUBJECT DEVICE

Name of Device: Beactive® Brace
Common or Usual Name: Orthosis, limb, for back pain
Classification Name: Limb Orthosis
Regulatory Class: Class I Exempt
Product Code: PMV
Classification: 21 CFR 890.3475

III. PREDICATE DEVICE

Primary	K821582	Warm'n Form Sports Supports (Jerome Medical)	Product Code IQI 21 CFR 890.3475 Limb Orthosis
Reference	K003128	Modification to Relief Brief (The JM Kohn Co.)	Product Code NJB 21 CFR 890.3490 Truncal Orthosis

IV. DEVICE DESCRIPTION

The Beactive® Brace is a brace intended to temporarily reduce lower back pain that radiates down the leg associated with normal household or work activities. The Beactive® Brace is an adjustable, cylindrically-shaped band that fits over the upper calf on either leg. Integrated into the wall of the brace is a disk-shaped protrusion (pressure pad) that projects inward toward the leg. The pressure pad presses against the soleus muscle located just to the outside of the back of the knee. The pressure pad exerts even pressure on the soleus muscle near its origin at the fibula. The Velcro strap is designed to focus the pressure on the pressure pad on the calf. As a soleus muscle compression brace, it uses both compression as well as anterior glide forces onto the proximal tibiofibular joint to temporarily reduce low back pain.

V. INDICATIONS FOR USE

The Beactive® Brace is applied to the to the upper calf just below the knee such that the pressure pad presses against the soleus muscle located just to the outside of the back of the knee for the purposes of temporarily reducing lower back pain that radiates down the leg associated with normal household or work activities. The Beactive® Brace is intended for over-the-counter distribution.

VI. COMPARISON WITH THE PREDICATE DEVICE

Spasms of the soleus muscle cause the fibular head to move in posterior direction, which strains the peroneal nerve. The Brace falls within the definition of 21 CFR 890.3475 because it provides pain reduction by repositioning the fibular head, which aligns body structures for functional improvement or corrects deformities. It is similar to a limb orthosis such as K821582 supports lower limb structures. The reference predicate was cleared for use as a lumbo-sacral support and as an acupuncture device for the purpose of reducing menstrual pain symptoms (including cramps, abdominal pain, and backache) and reducing pain medication use associated with menstruation.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the Beactive® Brace was conducted and the battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

Clinical Study

Primary effectiveness endpoint: Subjects evaluated the pain they experienced on a standard 10-point pain scale. They evaluated the worst and least pain:

- before using the Brace (qualifying),
- while performing the motion that caused the worst pain after applying the Brace,
- while at rest when wearing the Brace, and
- after a week of wearing the Brace.

Secondary effectiveness endpoint: Subjects completed an Oswestry Disability Index Questionnaire before wearing the brace and after a period of time (four days or one week) of wearing the Brace.

Effectiveness

The clinical trials provide evidence that the Beactive® Brace temporarily reduced low back pain that radiates down the leg associated with normal household or work activities for a majority of subjects

and produced clinically significant reduction in pain ($\geq 30\%$) in 52% of subjects. The pain index reported at 15 minutes and 1 hour while performing activity or being in the position in which the pain was worst declined clinically significantly 32% at 15 minutes and 40% at 1 hour. In the case of the Beactive® Brace studies, a minority of subjects reported no change or an increase in pain score. Labeling cautions that the user should cease using the brace and consult a physician if the pain increases.

Similarly, the scores for the disability index before and after the study demonstrate a clinically significant improvement in 12% of subjects in the treatment group.

Safety

Subjects experienced no adverse events during the clinical trials. Some subjects experienced an increase in pain; however, the instructions caution that the user should cease using the Brace if they experience an increase in pain. Some individuals may be sensitive to the materials of the Brace; however, labeling cautions that the user should stop using the Brace if the skin becomes irritated.

Summary

Based on the clinical performance as documented in the clinical study, the Beactive® Brace was found to have a safety and effectiveness profile that is similar to other limb orthosis devices.

VIII. CONCLUSION

The intended use of the Beactive® Brace is the same as other limb orthosis devices with the additional indication of temporarily reducing low back pain that radiates down the leg associated with normal household or work activities. The primary predicate K821582 Warm'n Form Sports Support is a limb orthosis that provides firm support of the muscles and stimulates an injured leg to provide gentle compression. The referenced predicate K003128 is a truncal orthosis device that is indicated for reducing pain symptoms. The Beactive Brace's pressure pad is a different technology from typical limb orthosis devices. However, it raises no new safety issues. Clinical studies show that it is effective in temporarily reducing low back pain that radiates down the leg associated with normal household or work activities. Therefore, the subject device is substantially equivalent to the predicate devices.

--- END OF 510(K) SUMMARY ---