

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

PLYMOUTH DIRECT, INC.)	
)	
and)	
)	C.A. No. _____
NATURES PILLOWS, INC.,)	
)	
Plaintiffs,)	
)	
vs.)	
)	
UNITED STATES FOOD)	
AND DRUG ADMINISTRATION)	
)	
and)	
)	
UNITED STATES OF AMERICA,)	
)	
Defendants.)	

DECLARATION OF BRAD SPECTER

I, Brad Specter, hereby declare as follows:

1. I am the co-President of Natures Pillows, Inc. (“NPI”), and I have held this position since the time that the company was founded in 1993. I work in NPI’s sole office. The business address is 2607 Interplex Drive, Trevose, Pennsylvania.

2. I make this Declaration based upon my personal knowledge. I am responsible for NPI’s business affairs, particularly with respect to marketing, distribution, sales, and related matters. I have more than 35 years of experience in marketing and selling consumer products, particularly through retail and mail order channels.

3. I have direct knowledge concerning NPI's business and customer relationships in the United States, as well as the market for products imported and sold by NPI, including the BeActive® Brace ("Brace") (BEACTIVE® is a registered trade mark). I also understand the harm that NPI faces as a result of the United States Food and Drug Administration's ("FDA") actions concerning the detention of NPI's Braces. For the financial information addressed in this Declaration, I relied on information regularly recorded and maintained by the company in the ordinary course of its business.

4. NPI is a small company. Our business depends on bringing innovative products to the market, and we focus on introducing one or two new key products each year. NPI has approximately eight key competitors, with each typically marketing ten or more new products each year.

5. NPI's business depends greatly on successfully selling its new products. NPI maintains its market share, and remains profitable, by selling a large volume of new products each year, on small margins. In addition, a large volume of new product sales is essential for NPI to maintain its customer relationships and generate funds to meet NPI's daily financial obligations.

6. NPI invests significant time and money to bring its new products to market and to establish a brand presence and demand for those products. NPI's product investments ordinarily include, for example, millions of dollars related to television commercials, toll-free telephone numbers, internet marketing, and other activities. NPI has made such investments to bring the Brace to market.

7. NPI has a joint venture relationship with Plymouth Direct, Inc. (“Plymouth”). Plymouth markets and sells the Brace primarily through television advertising and commercials. NPI markets Braces through retail and mail order channels. NPI and Plymouth share the profits resulting from their sales of products.

8. Plymouth’s television-based sales of the Brace increase the demand and market for the Brace and support NPI’s ability to sell that product through retail channels, including catalogues and retail stores. Plymouth’s ability to market and sell Braces is important to NPI’s ability to market the products in retail channels. FDA’s detention of Braces owned by Plymouth is extremely detrimental to NPI’s business, including because: (1) many retailers are more willing to stock products only if they are “As Seen on TV,” i.e., as offered by Plymouth; (2) NPI has touted this as a product marketed on television to retail customers, and a cessation of television sales will adversely impact NPI’s credibility and relationships with those customers; and (3) as television sales decrease for lack of supply, retail sales by NPI’s customers are likely to decrease, decreasing NPI’s own sales.

9. FDA’s detention of Braces threatens to destroy NPI’s business, unless the detained products are immediately released for distribution and NPI can continue to import and sell Braces in the U.S.

10. The detained Braces that were shipped to the U.S. for NPI are now owned by NPI. NPI ordered those products from Base4 Group Inc. (“Base4”), NPI’s supplier. Base4 is the Importer of Record for this product, and NPI is the Owner and Consignee of shipments that it orders to be imported by Base4. After ordering Braces from Base4, NPI

is required to take possession and ownership of those products as they arrive in the U.S., and cannot cancel with Base4.

11. Although it owns its detained products, NPI does not obtain any funds or revenue for Braces until after those products are shipped to NPI's customers. When a Brace is shipped to a customer, that shipment results in a receivable on the customer's account. Based on this receivable, NPI's lender will advance funds to NPI. NPI then uses these funds to pay for the original shipment of those products received by NPI.

12. When the FDA detains products at the border, NPI is unable to ship those products to customers, unable to obtain revenue, and unable to pay for those products.

13. The FDA's detention of Braces at the U.S. border has a devastating impact on NPI's business. This impact includes the inability to pay for ordered products, the inability to continue its business due to a lack of funds, the likely loss of customer relationships, a serious risk of competitive harm and loss of market share, and exposure to significant claims and potential liability to NPI's supplier and customers.

14. NPI has sold Braces in the U.S. from August 2014 through October 2014, during which time NPI sold \$4,700,980.36 of that product, corresponding to sales of more than 600,000 units.

15. Customer satisfaction regarding Braces is exceptionally high. On NPI's shipped products that total \$4,700,980.36, NPI has received returns from retailers amounting to only \$24,133.67. This corresponds to a return rate of only 0.51%, which is well below the standard rate of return in the industry, and reflects an extraordinarily high level of customer satisfaction with the Brace.

16. Customer orders for Braces have increased each week. A total of more than 2,265,000 units have been ordered by customers in the U.S.

17. NPI currently has received pending orders for more than 1.5 million units, with delivery dates from now through the end of this year. Most significantly, the bulk of these orders are from major retailer customers who ordered Braces to sell during the most critical retail season of the year, including now through “Black Friday.” To meet this urgent demand, NPI has ordered a huge number of Braces from its supplier to be shipped for expedited delivery (via air freight).

18. Between October 27, 2014 and November 3, 2014 alone, NPI’s customers expect to receive delivery from NPI of more than 740,000 units of Braces. Because of FDA’s detention of shipments, however, NPI cannot deliver those products. FDA recently has detained hundreds of thousands of units that customers are expecting from NPI.

19. The resulting harm to NPI is growing, and will continue to escalate, each day that NPI is unable to deliver Braces to customers in the U.S. The economic harm to NPI increases each day, and already includes millions of dollars related to currently detained product (cost of goods and lost revenue, as well as potential penalties and claims from customers). As discussed below, NPI faces likely insolvency, and loss of customer relationships, reputation, good will and market share.

The Be Active® Brace Is NPI's Most Successful Product

20. The Brace is a wrap-style brace for placement on a leg, creating a pressure at a specific point on the calf muscle causing the muscle to relax in a way that reduces tension on the sciatic nerve thereby reducing lower back pain.

21. The Brace is on track to be the most successful product that NPI has ever sold in the history of the company, in terms of the number of units sold and profitability.

22. Since NPI began importing the Brace on or about September 2, 2014, the Brace has accounted for the majority of NPI's sales revenue for orders received to date. The Brace is NPI's most important product. NPI's sales of Braces exceed the total combined sales of NPI's eight other products in 2014.

23. NPI continues to receive weekly orders for hundreds of thousands more units. All of this business will be lost, however, unless the products detained by FDA are released immediately and can be promptly delivered to customers, and future shipments and entries can be imported without automatic detention.

24. The urgency of this supply chain to NPI and its customers is compounded, moreover, because retailers are now stocking product for the approaching holiday season, which is the most important time of the year to retailers. If NPI is unable to quickly remedy its loss of supply and fill retail orders, then the retailers will move quickly to reallocate retail shelf and store space to competitors' products. Time is of the essence so that NPI can attempt to preserve its premier product placement and allocation status. In addition, catalog companies have placed the Brace on the coveted holiday cover and are receiving orders for those products. If NPI cannot supply as many products as those mail

order companies expected to sell, those companies may assert claims against NPI. The same is true for NPI's large retail customers, who may claim millions in lost dollars.

25. Since NPI first shipped Braces, and for the period August 2014 through October 2014, this product represents approximately 60% of NPI's total sales revenue. The Brace also accounts for more than 50% of NPI's total unit sales, for all products, during that time period.

26. Although NPI did not sell Braces for most of 2014, Brace sales are projected to account for 70% or more of NPI's entire annual sales for 2014, based on surging demand, if NPI can promptly resume importing and delivering those products.

More than 600,000 BeActive® Braces Were Imported and Sold in the U.S.

27. NPI launched sales of the Brace in August 2014. Before that time, in April 2014, the FDA evaluated and affirmatively confirmed in writing that this product can be lawfully imported and sold in the United States without any advance pre-market clearance or regulatory approval from the FDA.

28. On April 11, 2014, Kim Yzaguirre (identified as Base4's Director of Operations) sent an email to Ms. Sylvia Gaytan at FDA, with pictures, so that FDA could review and confirm the classification for the Brace. A copy of Ms. Yzaguirre's April 11, 2014 email, with sample pictures that were attached, is attached as Exhibit A. In response, on April 24, 2014, Ms. Gaytan at FDA sent an email to Ms. Yzaguirre forwarding the classification response from FDA's "HQ," confirming FDA's position. A copy of FDA's April 24, 2014 email confirmation is attached as Exhibit B. I received the emails attached as Exhibits A and B on June 3, 2014, from Jon Filipski at Base4.

29. After FDA's confirmation, and in reliance upon it, NPI invested significantly to bring the Brace to the U.S. market. For example, NPI established business relationships to arrange for companies to purchase Braces from manufacturers in China and deliver large quantities of those products to be imported in the U.S. In addition, NPI invested in marketing and promotion of Braces, secured multiple sales channels and customers for the Braces, and accepted purchase orders for millions of Braces from those customers. NPI, in turn, placed its own orders for Braces to supply to NPI's customers, with NPI required to pay for those products as they arrive in the U.S.

30. All of the suppliers who manufacture Braces are located in China. No company has manufactured Braces in the U.S. Therefore, all Braces sold by NPI in the U.S. have to be imported from China. Because of the urgent need to expedite delivery to the U.S. to meet retail demands for the holiday season, NPI is paying for air freight, at a much higher cost than standard water freight charges.

31. After FDA's written confirmation, NPI has ordered millions of Braces. As each shipment arrives in the U.S., NPI is required to pay for that shipment. To make those payments, however, NPI first must ship the products to its customers, to create the receivable against which NPI borrows funds from its financial institution.

32. In August and September 2014, NPI received several shipments of Braces from China. As of October 2, 2014, more than 200,000 Braces were imported into the U.S., without any problem.

33. Subsequently, additional shipments of Braces arrived in the U.S. After initially holding shipments and detaining three of them, FDA later released all of these units, and NPI was able to deliver these products to customers in the U.S.

The FDA Is Detaining Hundreds of Thousands of BeActive® Braces

34. Now, the FDA is refusing to permit shipments of Braces to enter the U.S. as they arrive from China by automatically detaining each shipment as it arrives.

35. Currently, FDA has detained more than 230,000 units of Braces that are owned by NPI. This does not include additional detained Braces owned by Plymouth.

36. On November 3, 2014, more than 158,000 additional units of Braces, already in transit to the U.S. by ship or air, are scheduled to arrive and expected to be detained by the FDA. All of those products were ordered by NPI. Further, NPI has ordered hundreds of thousands more units from its supplier for the holiday retail season. This does not include additional incoming shipments of Braces to Plymouth.

FDA's Detention of BeActive® Braces Threatens To Destroy NPI

37. NPI is unable to ship detained products to customers, and thus unable to pay for those products or generate sales revenue for those products.

38. NPI's estimated lost revenue on existing orders alone will exceed \$13 million, which is more than half of NPI's revenue on all sales, for all products, from January 1 through October 31, 2014.

39. In addition, NPI faces the threat of demands from its supplier for millions of additional dollars to pay for the products detained in the U.S. and for additional pending orders for products.

40. Further, NPI faces the threat of demands from customers for millions more in penalties, as well as claims for lost sales or profits, as a result of NPI's inability to deliver detained products. The additional claims, including anticipated customer "charge backs" related to detained products, are estimated to range from more than \$7 million to more than \$17 million.

41. During the week of October 27, 2014, NPI was unable to deliver hundreds of thousands of Braces that customers ordered, due to insufficient inventory on hand. Walmart, for example, was scheduled to receive more than 260,000 Braces during the week of October 27, which NPI is unable to deliver due to FDA's detention.

42. During the weeks of November 3, 2014 and November 10, 2014, NPI's various retail customers are expecting NPI to deliver more than 740,000 additional units of Braces, in response to existing orders.

43. The FDA's detention of Braces, now and in the future, is severely harming NPI, including with respect to:

- a. the likely loss of NPI's customers due to NPI's inability to supply detained products ordered by NPI customers;
- b. the loss of future business and sales channels, because of the loss of customers and damage to NPI's customer relationships;
- c. harm to NPI's goodwill and reputation, due to its inability to supply products ordered by customers;
- d. loss of market share that NPI will not be able to recover; and

e. the inability to continue operations due to the lack of sufficient capital and revenue.

44. The FDA's detention of Braces is also causing severe, ongoing economic harm to NPI, including with respect to:

a. more than \$2 million in estimated financial losses for hundreds of thousands of units of Braces that NPI is unable to pay for, as those products are currently detained by FDA, and cannot be distributed to customers;

b. lost revenue concerning at least 1,650,000 units of Braces that NPI's customers have ordered, to be delivered on an ongoing basis from now through December 2014, as those products cannot be delivered to customers;

c. future lost sales, based on orders that NPI would have received for customers, but now will not receive because NPI is unable to import or supply those products;

d. losses associated with the sunk costs, and time and money invested by NPI, including in efforts to market the products and promote the brand for Braces, as well as costs associated with displays, packaging, and other similar costs. These costs, as of October 31, 2014, are estimated to total more than \$500,000. When adding NPI's purchase investment in the product, with packaging and merchandising costs, NPI invested more than \$4 million to launch the Braces.

45. Further, as a result of NPI's inability to supply customers with ordered Braces, NPI faces an overwhelming exposure to claims and liabilities. NPI customers are likely to assert claims and demands against NPI. Customers who do not promptly receive the products that they ordered will issue "charge backs" for those products, cancelling their orders instead of issuing receivables to NPI. In addition, those customers are likely to seek payment of penalties under contracts, and customers also may seek additional sums for lost profits or lost sales.

46. The failure to deliver products to customers, as ordered, therefore exposes NPI to substantial and likely claims by suppliers and customers.

47. NPI will be unable to recover any of the millions of dollars in losses from the FDA, as the FDA will assert that the government has no liability as a result of sovereign immunity.

NPI's Customer Relationships Are In Serious Jeopardy

48. Through many years, NPI has established and cultivated relationships with its customers. Maintaining customer relationships is critical to NPI's business and ability to operate and sell products.

49. Because NPI is unable to fill orders from customers, NPI faces substantial harm to its business.

50. Every week, NPI's customers are ordering thousands of Braces from NPI.

51. The failure to fill orders from customers is likely to damage NPI's business and customer relationships severely and permanently.

52. NPI sells the Brace through multiple distributors that supply more than one thousand individual sellers, from kiosks in shopping malls to supermarket stores. In addition, NPI sells Braces to more than 25 retail customers, including direct response customers and retail chain customers.

53. The direct response NPI customers include mail order companies selling through catalogues. The retail store NPI customers for Braces include, for example, Walmart, Bed Bath & Beyond, Sears, CVS, Walgreens, Rite Aid, and Target stores. NPI's sales to retail customers constitute the vast majority of the company's sales -- as much as 90% of sales.

54. NPI is a small vendor to large retailers such as Walmart. Customers such as Walmart have already relied on the anticipated supply of Brace products from NPI, in planning promotions and inventory management. Currently, I understand that the Brace is Walmart's number one selling item in its product category.

55. NPI customers have, for example, allocated retail floor or shelf space for Brace products, designed catalogues promoting the Brace on the cover, and engaged in other marketing and promotional efforts.

56. If NPI fails to supply the Brace to customers, then NPI customers will likely discontinue doing all business with NPI. In addition, retailers highly value their retail store space and will likely deem unacceptable any failure by NPI to provide product for space that has been allocated by the retailer. Thus, the FDA's actions create a direct and irreversible threat to NPI's customer relationships.

57. Once a major customer is lost, NPI loses an important sales channel for its business. As an example, Walmart's business accounts for more than 25% of NPI's sales.

58. NPI's business requires products to be supplied on a very prompt basis to NPI's customers. In supplying products to Walmart, for example, the products are to be delivered within four days of entering the U.S.: the products enter the U.S. through Customs and Border Protection upon arrival (Day 1), the products are transported to a warehouse and assembled (Days 2-3), and the products are delivered to Walmart for pick-up at the warehouse (Day 4).

59. NPI's failure to fill customer orders for Braces results in a substantial threat - and likelihood - that customers will cancel those orders, and seek additional penalties and payments from NPI. NPI estimates that claims by customers for cancelled orders could range from approximately \$7 million to \$17 million. NPI would be unable to pay such claims.

60. In addition, those customers will likely refuse to do business with NPI in the future, regarding current or future products.

61. Unless the Braces can immediately be imported into the U.S. without detention by the FDA, NPI faces a real and imminent threat to its viability. NPI cannot continue to operate its business if it is unable to fill customer orders and supply customers with Braces.

FDA's Detention of BeActive® Braces Harms NPI in the Marketplace

62. FDA's actions preventing importation of Braces will damage NPI's reputation in the market and cause other competitive harm.

63. NPI's customers cannot market products that cannot be supplied by NPI, and are likely to discontinue all orders and sales of Braces, as well as of other NPI products.

64. NPI's customers have the option of selecting which products to market, and pick and choose among products offered by NPI and NPI's competitors. NPI's competitors offer a greater number of products than the products offered by NPI. It is foreseeable and likely that NPI's competitors will succeed in substituting some of their products for NPI's products.

65. NPI's loss of important sales channels, and specific customers, is itself an irreparable harm. In addition, NPI's competitors will have an opportunity to convert those sales opportunities for their own benefit, increasing their market share and relationships with NPI's customers, at NPI's loss and expense.

66. The FDA's detention of products has shut down NPI's distribution channel for Braces, impacting numerous customers and hundreds of retail outlets across the country, and undermining NPI's relationships with its customers.

NPI Urgently Needs Relief from the Court

67. NPI's business cannot be sustained without the ability to continue sales of its leading product, the Brace. Without the ability to import and sell this product, NPI will lack revenue sufficient to meet its expenses, and faces enormous harm.

68. NPI requests that the Court provide an immediate remedy to avoid the destruction of its business, which is likely to occur within days, unless NPI can resume immediately the importation and delivery of Braces to customers.

I swear under penalty of perjury that the foregoing is true and correct.



Brad Specter

Dated this 2nd day of November 2014.

EXHIBIT A

From: Jon Filipski [<mailto:Jon@ebase4.com>]
Sent: Tuesday, June 03, 2014 5:15 PM
To: erica.tv@comcast.net
Cc: Brad Specter
Subject: FW: KNEE BRACE IMAGES

Sure, here was her original email to the FDA for opinion.

Thank you,

Jon Filipski

BASE4 Group Inc
2611 Westgrove Drive, #109
Carrollton, TX 75006
P: 972-392-9090
F: 972-392-9169

From: Kim Yzaguirre [<mailto:Kim@ebase4.com>]
Sent: Friday, April 11, 2014 2:38 PM
To: 'sylvia.gaytan@fda.hhs.gov'
Subject: FW: KNEE BRACE IMAGES

Sylvia

Thank you so much for helping. Like I said after reading through the FDA site on Medical devises I was not clear about ours.

Brace for relief of the sciatica nerve

The attached pictures are of the device the helps "ease the discomfort of sciatica".

The brace fits around the calf right below the knee and applies pressure to the soleus muscle in the calf and this eases the tension on the sciatic nerve.

Please help me determine if this is Class 1 501(K) exempt. The other braces I found were Class 1 501(K) exempt but I could not find a listing that specified a brace that fits around the knee for easing back discomfort.

Thank you,
Kim Yzaguirre
Base4 Group
Director of Operations
2611 Westgrove Dr
Suite 109
Carrollton Texas 75006
Phone 972-331-6623
Fax 972-392-9169
kimy@ebase4.com

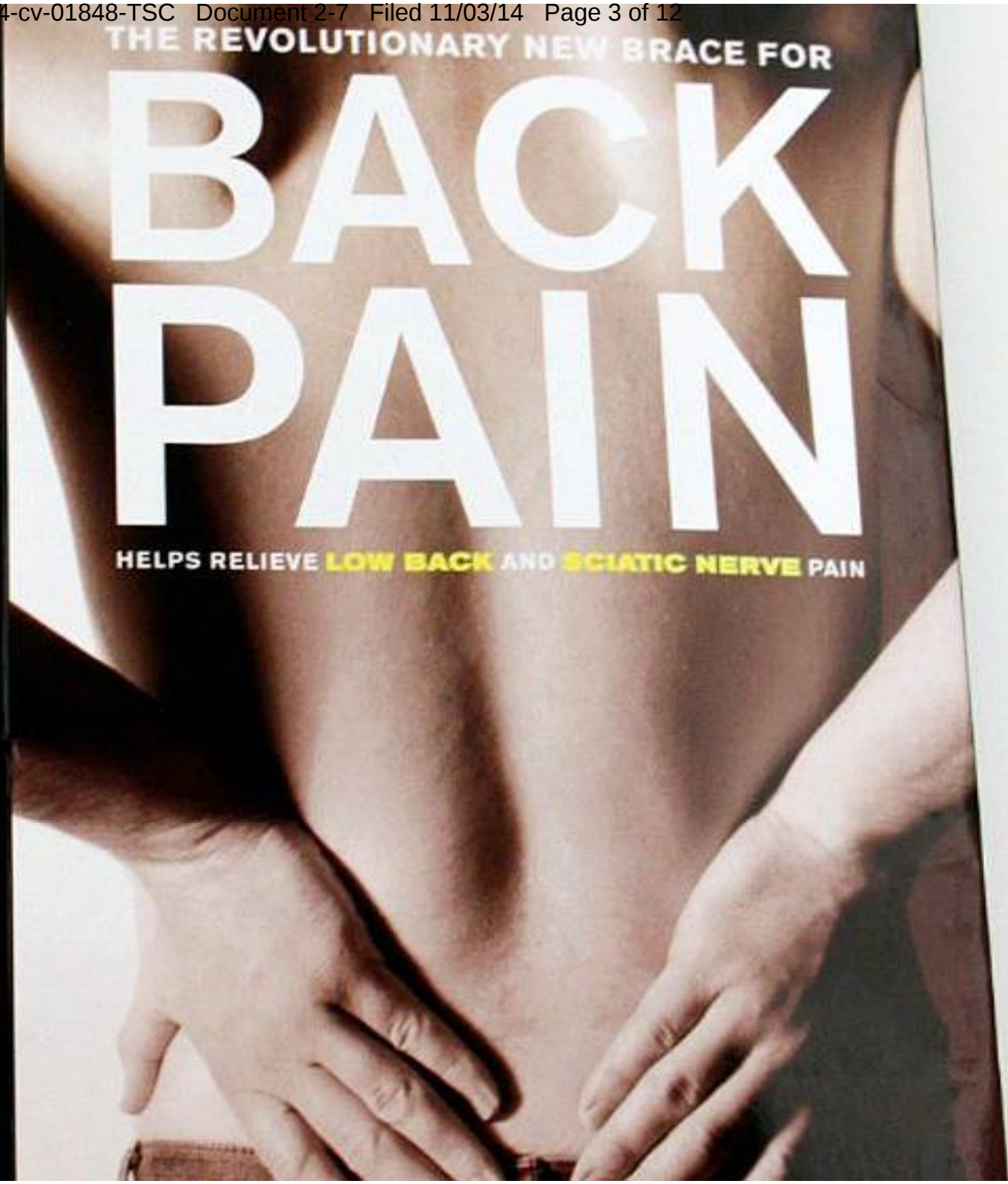
unisex brace for low back pain



THE REVOLUTIONARY NEW BRACE FOR

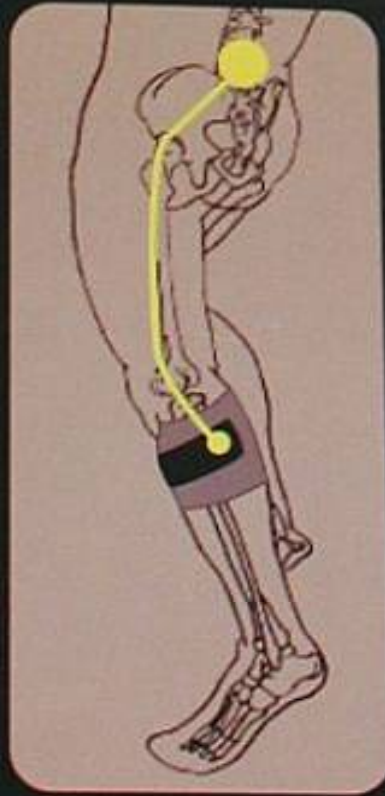
BACK PAIN

HELPS RELIEVE **LOW BACK** AND **SCIATIC NERVE** PAIN



unisex brace for low back pain

The BeActive pressure brace uses a revolutionary pain relief technology to target **LOW BACK** pain. When the pressure is applied to the soleus muscle in the calf, it releases tension in the sciatic nerve through the knee to the low back.



Apply brace using 3 simple steps:

1. Slip brace on until it rests just under knee. If pain is on right side, put brace on right leg with the R on top. If pain is on left side, put brace on the left leg with the L on top.
2. Make sure R or L is centered below the knee, and the pressure dot is on the outer edge of the calf muscle.
3. Tighten strap to apply firm pressure on to your calf.



FRONT



BACK

Example shown with left leg.

note: If pain is toward the middle lower back apply brace to right leg. If there is no improvement flip brace and apply to left leg.













EXHIBIT B

From: Jon Filipski [<mailto:Jon@ebase4.com>]
Sent: Tuesday, June 03, 2014 4:36 PM
To: Brad Specter; erica.tv@comcast.net; 'Bill McAlister'
Subject: FW: KNEE BRACE IMAGES -

See FDA email below ...

Thank you,

Jon Filipski

BASE4 Group Inc
2611 Westgrove Drive, #109
Carrollton, TX 75006
P: 972-392-9090
F: 972-392-9169

From: Kim Yzaguirre [<mailto:Kim@ebase4.com>]
Sent: Tuesday, June 03, 2014 3:31 PM
To: Jon Filipski
Subject: FW: KNEE BRACE IMAGES -

FDA response

Thank you,
Kim Yzaguirre
Base4 Group
Director of Operations
2611 Westgrove Dr
Suite 109
Carrollton Texas 75006
Phone 972-331-6623
Fax 972-392-9169
kimy@ebase4.com

From: Gaytan, Sylvia E [<mailto:Sylvia.Gaytan@fda.hhs.gov>]
Sent: Thursday, April 24, 2014 10:09 AM
To: Kim Yzaguirre (Kim@ebase4.com)
Subject: FW: KNEE BRACE IMAGES -

Ms. Yzaguirre,

Here is the response from HQ.

Thank you for your patience.

Respectfully submitted

From: CDRH OC Import Mailbox
Subject: RE: KNEE BRACE IMAGES -

Thank you for your patience while waiting for our response on the subject. CDRH has determined that the brace as described below would fall under 21 CFR 890.3475 as Class I, 510(k) exempt. However, your firm will have to register and list the product and comply with the general requirements for record and complaint files.

From: Kim Yzaguirre [<mailto:Kim@ebase4.com>]
Sent: Friday, April 11, 2014 2:38 PM
To: Gaytan, Sylvia E
Subject: FW: KNEE BRACE IMAGES

Sylvia

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Thank you,
Kim Yzaguirre
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Suite 109
Carrollton Texas 75006
Phone 972-331-6623
Fax 972-392-9169
kimy@ebase4.com