K063098

510 K Summary of Effectiveness and Safety

The following summary is provided in pursuant to Section 513 (I)(3)(A) of the Federal Food, Drug and Cosmetic Act.

APR 11 2007

1) Applicant Information

i) Submitter: Boston Brace International, Inc., 20 Ledin Drive, Avon, MA 02322

ii) Contact: James Wynne, CPO, Director of Education, Boston Brace International,
Telephone (508) 588-6060 ext. 244

iii) Summary Date.-Feb 16, 2006 V B.

2) Device Name and Classification:

i) Proprietary Name: Boston Band Cranial remolding Orthosis

ii) Common Name: Cranial Orthosis

iii) Classification Name: Cranial Orthosis, laser scan, OAN

iv) Predicate Device: STARband Cranial Remolding Orthosis, (K011350), classified under 21 CFR £ 882.5970

3) Device Description

The Static Cranioplasty Orthosis is a cranial orthosis used to treat abnormally shaped craniums in infants three to 18 months of age. This condition is clinically known as positional or Deformational Plagiocephaly. The orthosis contains the protruding aspects of the cranium in a static equilibrium while guiding the growth of the flattened-areas of the skull into the created spaces. The Static Cranioplasty Orthosis is only available if prescribed by a physician.

The orthosis is custom designed for each patient from a cast of the infant's head or a scan using the STARscanner from Orthomerica . The mold, either plaster from the cast, or foam from the scan, is modified and prepared for fabrication by the treating practitioner using mathematical analyses and plaster modification techniques. The orthosis is then fabricated under the direction of the same practitioner. Each orthosis is composed of an outer shell of thermoformable plastic, 5-6 layers of hypoallergenic polyethylene foam and a strap for securing the orthosis. Optimum fit and alignment is insured and monitored by the same clinical practitioner.

4) Intended Use

The Static Cranioplasty Orthosis is intended for medical purposes to passively hold prominent cranial regions of an infant's skull in order to improve cranial symmetry and/or shape in infants from three to eighteen months of age, with nonsynostotic positional plagiocephaly, including infants with plagiocephic, brachycephalic and scaphocephalic patterned head shapes.

5) Comparison to Predicate Device

The Static Cranioplasty Orthosis and the predicate device are very similar with respect to production, instructions for use, materials, safety and effectiveness and special controls. The main difference is the use of Velcro hook strap attached to a self adhesive loop, versus a chafe loop system, and the thickness and layers of the polyethylene foam. The thin layers of foam allow selective voids to aid in the ability to guide growth.

The material is handled in an identical manner to the polymer used in the predicate device, incorporating all of the safety and standards of practice. The proposed indications of use are analogous to those presented by the predicate device, and biocompatibility, function and effectiveness further parallel those of the predicate device.

See table next page.

Labeling	Predicate Device	Proposed device
Indications	Infants, 3 -18 months of age, with abnormally shaped craniums with no outstanding cranial abnormalities that have a RX from a physician who has assessed the child to rule out Craniosynostosis	Same
Contraindications	Infants with Craniosynostosis or hydrocephalus	Same
Warnings	Evaluate head circumference measurements and neurological status at intervals appropriate to the infant's age and rate of growth. Describe to caregiver steps that should be taken to reduce the potential restrictions of cranial growth and possible impairments to brain growth and development. A clinician or caregiver must evaluate the patient's skin at frequent intervals.	Same
Precautions	If the positional plagiocephaly is associated with torticollis, the torticollis must also be treated. Evaluate the device's structural integrity and fit it according to fitting instructions. Wear and care guide to be reviewed and provided to caregiver.(copy attached)	Same
Adverse Effects	This device may cause skin irritations or breakdown	Same
Intended use	Intended for medical purposes to passively hold prominent cranial regions of an infant's skull in order to improve cranial symmetry and or shape in infants with plagiocephaly, including infants with plagiocephalic, brachycephalic, and scaphocephalic patterned head shapes	Same
Instructions for Use	Wear and care guide provided to caregiver	Same
Expiration date	When the infant outgrows the cranial helmet or the orthosis is discontinued for any reason, the referring physician is contacted. If an other helmet is requested by the family to try to further correction, refer back to their physician for reevaluation and a new prescription.	Same

6) New Performance Data

1) The effectiveness of the Static Cranioplasty Orthosis has been established through clinical trials. (Orthotic Treatment Protocols for Plagiocephaly, Jeff Larson, CO;JPO 2004, Vol 16, Num 4s). The effects of treatment with cranial orthoses on infants have concluded that the devices are significantly effective in correcting abnormal head shape, without evidence of relapse following treatment. Treatment with cranial orthoses is reported to improve the results of surgical correction of severe cases, often eliminating the need for further surgical intervention. The predicate device is fabricated using th same techniques and materials (From Biocompatability: **The predicate device** designed by Orthomerica(K011350) incorporates an outer 3/16 Copolymer shell lined on its interior with a medium durometer crosslinked Polyethylene Foam, Volara(Ali-plast) lining.(Per web site www.orthomerica.com/products/cranial/starband.htm) **Description of Orthosis**

- Side-opening band
- Proximal Opening
- 3/16" copolymer shell
- 1/2" polyethylene foam liner
- 1 1/2" Velcro® strap and chafe closure

The safety of the cranial orthoses is established under standard biocompatibility assessments for each material used. These assessments reveal that the device and the materials used are not expected to adversely affect the infants under the intended conditions of wear.(Polyethylene foam is commonly used to line orthoses) The materials are not reported to cause skin irritation or any toxic effects. Further, the product is designed to avoid improper migration or harmful levels of pressure. The interior of the device is smooth and poses no significant threat to the child during application within the normal scope of its intended use.

7) Summary

The safety and effectiveness information submitted to the FDA establishes that the Boston Band Cranial Remolding Orthosis is safe and effective for its intended use and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 11 2007

Boston Brace International
% Mr. James Wynne, CPO
Director of Education/Training
20 Ledin Drive
Avon, Massachusetts 02322

Re: K063098
Trade/Device Name: Boston Band Cranial Remolding Orthosis
Regulation Number: 21 CFR 882.5970
Regulation Name: Cranial orthosis
Regulatory Class: II
Product Code: OAN
Dated: February 16, 2007
Received: February 22, 2007

Dear Mr. Wynne:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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 801); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Barbara Richardson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063098

Device Name: Boston Band Cranial Remolding Orthosis

Indications For Use:

Infants, 3 – 18 months of age, with abnormally shaped craniums with no outstanding cranial abnormalities that have a RX from a physician who has assessed the child to rule out craniosynostosis.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buehler

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063098