K063133 pg 1 of 4

JUL - 2 2007

CRANIAL SOLUTIONS

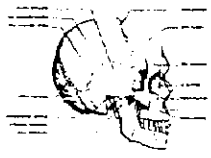
602 Lincoln Avenue Pompton Lakes, N.J. 07442-1309

Tel: (973) 835-7929

510(k) Summary

June 12 2007
Kirk A Lucyk, CO
Trade Name: Cranial Solutions Orthosis (CSO)
Classification Name: Cranial Orthosis
Classification # 882.5970
Code:MVA

The CSO is a custom made medical device intended to apply gentle pressure to prominent regions of the infant's cranium, and to provide realignment space for depressed cranial regions to improve symmetry and or shape.
The device is of thermoplastic construct. A semi-rigid outer shell of Orthopedic grade copolymer polypropylene thermobonded to a medium durometer polyethylene foam inner liner(Volara).The formula for the outer shell is [ch(ch3)ch2-] 90% polypropylene and 10% polyethylene.
By design the CSO is a dynamic orthotic device.
As a predicate selection for substantial equivalence I would like to reference the Dynamic Orthotic Cranioplasty (DOC) device and design.
The CSO and Cranial Technologies DOC device have the same indications for use: On infants three to eighteen months of age with moderate to severe non-synostotic positional plagiocephaly and other abnormal head shapes.



CRANIAL SOLUTIONS

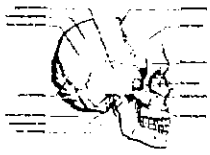
602 Lincoln Avenue Pompton Lakes, N.J. 07442-1309

Tel: (973) 835-7929

510(k) Summary Page 2

Both devices are Not intended for infant's with craniosynostosis or hydrocephalus. Both devices provide cranial orthotic treatment for infant's with nonsyndromic head deformity as a result of the utero process: e.g. compressional forces exerted by the lumbosacral spine, uterine malformation, fetal malpositioning, multiple fetuses oligohydramnios, and the current supine positioning recommendations. By design the CSO and DOC have a single lateral opening on the side adjacent to the flattened occipital-parieto region, provide a generous opening on top for air flow, and are very light in weight. Both devices can easily be adjusted for normal growth during the treatment process, and are easy to apply and remove by the care giver.

Both devices are of thermoplastic construction consisting of a semi-rigid outer shell bonded to a soft inner lining. Both outer shells are of Orthopedic grade plastic with hazard data all within OSHA permissible exposure limits with none know medical conditions aggravated by exposure. The CSO and DOC inner linings have been tested and approved by the FDA for long term skin contact. Both devices are of dynamic design , and when applied to an infant mild pressure, a low energy load , will constrain and correct abnormal growth . Normal growth will take place in the provided space and the cranial symmetry will be much improved.Standard treatment time for both cranial orthoses is three to four months.



CRANIAL SOLUTIONS

602 Lincoln Avenue Pompton Lakes, N.J. 07442-1309

Tel: (973) 835-7929

510(k) Summary

By design specifications and design intent the CSO is vacuum formed over a modified cranial model obtained from a plaster cast taken of the infant's calvarium . Both the cranial solutions orthosis and the predicate device are formed only after the cranial model has been corrected or restored to as near as complete symmetry as possible. This exact correction will produce a very accurate and effective fit.

In keeping with our goal: To provide the safest, effective, and most comfortable cranial orthosis on an individual, custom, and prescription basis we at Cranial Solutions employ an important clinical tool. Our CSO Anthropometric measurement form.

After obtaining the plaster impression we complete this form and explain it to parent or care giver. By encouraging the parents to be involved in the measurements(progress) they will keep and understand the need for biweekly follow-up appointments.

By having the cranial orthosis and head circumference evaluated and recorded at preset intervals by the practitioner the risk factors can be reduced and the infant will have a much improved clinical outcome with their cranial orthosis.

CRANIAL SOLUTIONS
602 Lincoln Avenue
Pompton Lakes, NJ 07442
(973) 835-7929

CRANIAL SOLUTIONS ORTHOSIS

The use of this device (CSO) is restricted to prescription use only by order of a Physician.

INTENDED USE: The CSO is intended for use on infants from three to eighteen months of age with moderate to severe non-synostotic positional plagiocephaly , including infants with plagiocephalic, brachycephalic,and scaphocephalic shaped heads.The CSO is intended to apply gentle pressure to prominent regions of the infants's cranium, and to provide realignment space for depressed cranial regions to improve cranial symmetry and or shape.

CONTRAINDICATIONS: The Cranial Solutions Orthosis (CSO) is contraindicated for infant's who have synostosis or hydrocephalus.

WARNINGS: All infants being treated with a cranial orthosis need to have their head circumference evaluated, measured, and recorded at preset intervals by a practitioner. also neurological status and rate of head growth must be evaluated at age appropriate intervals to reduce the risk of restricting normal cranial growth and brain development. Parents or care givers need to examine, evaluate, and monitor the infant's skin every 3 to 4 hours of use; if skin irritation or breakdown occurs the orthosis must be removed and the practitioner must be called or consulted.Parents please remember that proper adherence to the care and usage instructions is necessary to reduce potential restriction of cranial growth, brain development, and your child's safety and comfort.

PRECAUTIONS: Parents or care giver be advised that if your child has torticollis it should also be treated additionally with the positional plagiocephaly.When receiving cranial orthotic treatment your child's device must be evaluated for fit and function on a preset and regular basis to avoid skin irritation, growth impairment, and assure normal brain development. It is also important to have your device checked or evaluated by your practitioner for structural integrity to reduce the potential to migrate out of place and cause asphyxiation, eye trauma, skin breakdown or prolonged discomfort.

ADVERSE EVENTS: Although your devices soft lining has been tested for long term direct skin contact; skin irritation can occur when using this device.However most skin irritation can be avoided by strictly following the cleaning, drying, and care and usage instructions.Remember, check your child's skin every 3 to 4 hours.The Orthosis should fit snug, apply gentle pressure, and NOT be overly tight. Please follow the instructions that were provided with your child's CSO device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 2 2007

Cranial Solutions
% Kirk A. Lucyk, C.O.
602 Lincoln Ave.
Pompton Lakes, New Jersey 07442-1309

Re: K063133/S2
Trade/Device Name: Cranial Solutions Orthosis (CSO)
Regulation Number: 21 CFR 882.5970
Regulation Name: Cranial orthosis
Regulatory Class: II
Product Code: MVA
Dated: May 9, 2007
Received: May 14, 2007

Dear Dr. Lucyk:

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 toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

For DSD 6/29/07

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): K063133

Device Name: CRANIAL SOLUTIONS ORTHOSIS (CSO)

Indications For Use:

The Cranial Solutions Orthosis is intended for use on infants from three to eighteen months of age with moderate to severe non-synostotic positional plagiocephaly,including infants with plagiocephalic, brachycephalic, and scaphocephalic shaped heads. The CSO is intended to apply gentle pressure to prominent regions of the infant's cranium, and to provide realignment space for depressed cranial regions to improve cranial symmetry and or shape.

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

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

Page 1 of ____

510(k) Number K063133