NOV 1 3 2003

510(K) Summary of Effectiveness and Safety

K021594

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

A. Applicant Information

Submitter: Center for Orthotic and Prosthetic Care of KY, LLC. 1010 Clarks Lane, Louisville, KY 40217. Phone: (812) 941-0966, Fax: (812) 941-0958, Email: copc@bluegrass.net

Contact: Keith Senn, Bob Havens, Center for Orthotic and Prosthetic Care of KY, LLC 1010 Clarks Lane, Louisville, KY 40217. Email: copc@bluegrass.net, Phone: (812) 941-0966

- **Summary Date:** October 15, 2003

B. Device Name and Classification (K021594)

- **Proprietary Name:** COPC Band
- **Common Name:** Cranial Orthosis
- **Classification Name:** Cranial Orthosis
- **Predicate Device:** DOC™ Band, Cranial Orthosis, K964992, classified under 21 CFR § 882.5970

C. Device Description

The COPC Band is a cranial orthosis used to treat abnormally shaped craniums in infants three to 14 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 COPC Band is only available through a prescription issued by a physician.

The orthosis is custom designed for each patient from a modified model and measurements of the infant's head. The mold is prepared for fabrication using advanced plaster modification techniques. Each orthosis is composed of an outer shell of thermoformable plastic, an inner lining of hypoallergenic foam, and a strap for securing the orthosis. Optimum fit and alignment is insured and monitored by the clinical practitioner.

D. Intended Use

The COPC Band 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 initiating treatment from three to 14 months of age, with nonsynostotic positional plagiocephaly, including infants with plagiocephalic, brachycephalic, and scaphocephalic patterned head shapes.

E. Comparison to Predicate Device

The COPC Band and the predicate device are very similar with respect to production, instructions for use, materials, safety and effectiveness, and special controls. The COPC Band combines an outer shell of thermo-formable polymer and hypoallergenic foam lining in an analogous fashion as the predicate device. The device fits the child in a similar fashion as the predicate device, with trim lines terminating over the same points. The primary difference between the proposed and predicate devices is the side closure strap of the orthosis, where the COPC Band incorporates two straps and the DOC Band utilizes a single strap. The COPC Band utilizes modified polyethylene and aliplast as the composite materials, and the DOC Band utilizes copolymer and aliplast as its composite materials. MSDS sheets for these materials confirm that they are safe, non-hazardous, and non-reactive with human skin under normal contact conditions and environments. 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.

F. Performance Data

The safety of the COPC Band 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, which are analogous to those for the DOC Band. 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. The COPC Band has incorporated within its clamshell design a natural corrugated stop, which prevents overtightening and harmful pressure upon the infant's skull. This safety feature heightens the COPC Band's safety above that of the predicate device in that the predicate device has no such inherent safeguard. The COPC Band's performance has been demonstrated and compared to the predicate device through an analysis of pressure exerted by the device upon the child's skull. Pressure sensors applied to a cranial model with a COPC Band applied, demonstrates quantifiably that intimate contact exists between the regions of cranial prominences, while no pressure exists in the regions of the cranial depressions as they are positioned over the corrective voids. This data and device performance is directly analogous with the regions of contact between the predicate device and the patient using the device.

G. Summary

The safety and effectiveness data submitted to the FDA establishes that the COPC Band is safe and effective for its intended use and is substantially equivalent to applicable predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 3 2003

Center for Orthotic and Prosthetic Care, LLC
C/O Joseph Terpenning, CO
2525 North Tenth St., #804
Arlington, Virginia 22201

Re: K021594
Trade/Device Name: COPC Band
Regulation Number: 21 CFR 882.5970
Regulation Name: Cranial Orthosis
Regulatory Class: Class II
Product Code: MVA
Dated: undated
Received: October 31, 2003

Dear Mr. Terpenning:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: COPC Band

Indications for Use:

Indications for Use Statement:

The COPC Band is intended for medical purposes to passively hold prominent cranial regions of an infant's cranium in order to improve cranial symmetry and/or shape in infants initiating treatment from three to 14 months of age, with nonsynostotic positional plagiocephaly, including infants with plagiocephalic, brachycephalic, and scaphocephalic patterned head shapes.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over the Counter Use** _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for Mark N Milhous

(Division Sign-Off)

Division of General, Restorative and Neurological Devices

510(k) Number K021594