K070694

510(k) Summary
(I.A.W. 21 CFR 807.87(h)

Applicant Information

Owner: Mike Miner
1098 E Mutton Hollow
Kaysville, Utah 84037
(801) 547-0369

SEP 10 2007

Contact: (As above)

Date:

Device Name and Classification

Proprietary name: Craniocephalic Custom Remolding Orthtosis

Common name: Cranial Helmet

Classification name: Cranial Orthosis

Predicate Device: LLUMC k023572, Ballert k030669, Clarren k003035

Device Description

The CCRO is a passive cranial orthosis that allows an infants cranium to improve in symmetry and/or shape during natural infant growth. Appropriate for infants 3 to 18 months, the CCRO consists of a polypropylene (or copolymer, or polyethylene as warranted), outer shell with multiple inner polypropylene foam liners of various thicknesses, and an optional support strap. The foam liners and outer plastic shell, are vacuum formed over a positive mold developed from an impression of the infant's head.

The orthosis allows applicable areas for the infant heads fill in during normal infant growth, to achieve appropriate cranial symmetry.

Intended Use

The CCRO is appropriate for improving cranial symmetry in infants from 3 to 18 months. The Craniocephalic Custom Remolding Orthosis (CCRO) is applicable for moderate to severe nonsynostotic positional plagiocephaly, including infants with plagiocephalic, brachycephalic, and scaphocephalic – shaped heads.

Comparison to Pediatric Device

The devices are made of the same materials, (all of which are also all widely used in the orthotic industry). The devices are also all fabricated through vacuum forming process; utilize the same csting/impression taking style, the same mold creation and modification regimens, and all function the ame way.

With the Craniocephalic Custom Remolding Orthtosis, the multipule liner system allows for increased precision and accuracy in adjustments during the ongoing follow up protocols.

These comparisons are presented in the comparison table found in the executive summary.

Conclusions

In comparison of the CCRO to its counterpart predicates, it is believed that the Craniocephalic Custom Remolding Orthtosis is equivalent if not an enhancement in effectiveness for patient care, and will perform as-well-as, if not better than its helmet counterparts to address treatment of nonsynostotic positional plagiocephaly, including infants with plagiocephalic, brachycephalic, and scaphocephalic – shaped heads.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 10 2007

Mr. Mike Miner
1098 East Mutton Hollow
Kaysville, UT 84037

Re: K070694
Trade/Device Name: Cranial Custom Remodeling Orthosis (CCRO)
Regulation Number: 21 CFR 882.5970
Regulation Name: Cranial Orthosis
Regulatory Class: Class II
Product Code: MVA
Dated: June 12, 2007
Received: June 12, 2007

Dear Mr. Miner:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

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

Enclosure

Indications for Use Statement

Indications for Use

510(k) Number (if known): _K070694___Device Name: __Craniocephalic Custom Remolding Orthosis _____

Indications for Use:

The Craniocephalic Custom Remolding Orthosis (CCRO), is indicated for infants 3 - 18 months old to improve cranial symmetry in moderate to severe nonsynostotic positional plagiocephaly, including plagiocephalic, braciocepahlic, and scaphocephalic heads.

Prescription Use **required** Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _N/A_ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K070694