JUL 2 5 2002 K021918

510(k) SUMMARY

Clarren Helmet (Orthomerica) and the STARscanner™

Orthomerica Products, Inc.

This 510(k) summary of safety and effectiveness for the Clarren Helmet and STARscanner is submitted in accordance with the requirements of SMDA and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant:	**Orthomerica Products, Inc.**
Address:	6333 N. Orange Blossom Trail Orlando, FL 32810 Deanna Fish, MS, CPO Clinical Education Manager (801) 265-1801 (telephone) (801) 265-1815 (fax)
Contact Person:	Deanna Fish, MS, CPO Clinical Education Manager (801) 265-1801 (telephone) (801) 265-1815 (fax) dfishcpo@aol.com
Preparation Date:	June 2002
Device Trade Name:	Clarren Helmet (Orthomerica)
Common Name:	Cranial Orthosis
Classification Name: Product Code:	Cranial Orthosis (see 21 C.F.R. § 882.5970) MVA
Device Description:	The Clarren Helmet is a cranial orthosis that applies passive pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape in infants from 3 to 18 months of age with moderate to severe nonsynostotic positional plagiocephaly. It consists of a polypropylene sheet, three-eights of an inch thick, which is vacuum formed over a plaster model of a baby's head to produce a helmet. A liner for the helmet is made of Plastizote, one-fourth of an inch in thickness. Small holes are bored in the helmet for ventilation, and large holes for the child's ears. A Velcro

chinstrap is attached to help keep the helmet in place on the baby's head. It is manufactured from a positive model, obtained via traditional manual casting methods or a three-dimensional scan of the infant's head.

Intended Use:

The Clarren Helmet is a cranial orthosis that applies passive pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape in infants from 3 to 18 months of age with moderate to severe nonsynostotic positional plagiocephaly, including infants with plagiocephalic, brachycephalic, and scaphocephalic- shaped heads.

Performance Data:

The Clarren Helmet (Orthomerica) –
Clarren, Sterling, M.D., "Plagiocephaly and torticollis: Etiology, natural history, and helmet treatment," *Journal of Pediatrics*, 98:1 (92-95) (Jan. 1981); Clarren, et al., "Helmet treatment for plagiocephaly and congenital muscular torticollis," *Journal of Pediatrics*, 94:1 (43-46) (Jan. 1979).

The STARscanner –
The STARscanner has previously received FDA clearance when used in conjunction with Orthomerica's STARband cranial remolding orthosis (K011350). The performance data demonstrates that the proposed automation of measuring for and carving a positive mold of the patient's head yields more accurate results than the manual process used for the predicate device. Specific information regarding the STARscanner is attached at Appendix D.

Conclusions:

The Clarren Helmet (Orthomerica) is safe and effective and identical to the Clarren Helmet (Children's Hospital). FDA has already reviewed and cleared the Clarren Helmet (Children's Hospital) based on performance data. FDA has also approved the use of the STARscanner in the fabrication of other cranial orthoses. Therefore, use of the scanner to fabricate the Clarren Helmet (Orthomerica) at Orthomerica's fabrication facility in Orlando, Florida raises no new issues of safety and effectiveness.

Based on the foregoing and other information in this application, Orthomerica Products, Inc. believes that the performance data provide reasonable assurance of the safety and effectiveness of the Clarren Helmet (Orthomerica) for its proposed indications for use. Further, the Clarren Helmet (Orthomerica) is substantially equivalent to its

claimed predicate, the Clarren Helmet (Children's Hospital) under conditions of intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 0 2007

Deanna Fish
Orthomerica Products, Inc.
6333 North Orange Blossom Trail
Orlando, FL 32810

Re: K021918
Trade/Device Name: Clarren Helmet (Orthomerica)
Regulation Number: 882.5970
Regulation Name: Cranial Orthosis
Regulatory Class: Class II
Product Code: OAN
Dated: June 7, 2002
Received: June 11, 2002

Dear Ms. Fish:

This letter corrects our substantially equivalent letter of July 25, 2002.

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 (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 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

This letter will allow you to continue 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 (see http://www.fda.gov/cdrh/organiz.html#OC for OC organization structure). 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/dsma/dsmamain.html.

Sincerely yours,

Mark N. Melkerson
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:_____

Indications For Use:

Indications for Use: The Clarren Helmet is a cranial orthosis that applies passive pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape in infants from 3 to 18 months of age with moderate to severe nonsynostotic positional plagiocephaly, including infants with plagiocephalic, brachycephalic, and scaphocephalic- shaped heads.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

for _____

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

510(k) Number K021918