510(k) Summary

OCT 31 2008

I. Applicant Information

- Applicant's Name and Address: Orthomerica Products Inc, 505 31st Street, P.O. Box 2927, Newport Beach, CA 92659, Telephone: (949) 723-4500, Facsimile: (949) 723-4501

  FDA Establishment Registration Number 1058152

- Contact: David C. Kerr, Chief Executive Officer, Telephone: (949) 723-4500, Facsimile: (949) 723-4501

- Submission Correspondent: Alan T. Sandifer, Director of Research and Development, 6333 North Orange Blossom Trail, Orlando, FL 32810, Telephone: (407) 290-6592, Facsimile: (407) 290-1303, asandifer@orthomerica.com

- Summary Date – October 1, 2008

II. Submission Information

- Type: 510(k) Device Modification (Special)
- Proprietary Name: STARlight
- Common Name: Cranial Orthosis
- Classification: Class II (special controls); OAN; MVA; 21 CFR 882.5970
- Classification Name: Cranial Orthosis
- Predicate Device: STARlight, Cranial Orthosis, K081994

III. Manufacturing Site: 6333 North Orange Blossom Trail, Orlando, FL 32810, Telephone: (407) 290-6592, Facsimile: (407) 290-2419, FDA Establishment Registration Number 1058152

IV. Description of Device

The STARlight redirects the head growth to improve proportion and symmetry. The practitioner takes a plaster impression or scan of the baby's head to acquire the existing shape. The mold is sealed and filled with plaster or the scanned shape is carved from a rigid polyurethane foam blank to create a positive model of the head shape. The positive model is modified to obtain greater symmetry and space in the areas of flattening. The STARlight provides total contact over the prominent or bossed areas of the baby's head to discourage growth there. Over the course of treatment, the inside of the band is modified further by the practitioner to provide space for growth to occur in the flat or depressed areas. The shape of the STARlight directs growth into the areas of least resistance and creates a precise pathway for the head shape to improve in symmetry and proportion.

The STARlight Side Opening design, STARlight Bi-Valve design and the STARlight Cap design are all made of a plastic shell of 5/32" – 1/4" clear Surlyn or 1/8" - 7/32" Clear Co-Polyester. The STARband Bi-Valve design is made with an outer shell of 5/32" polyethylene-polypropylene copolymer plastic and an inner liner of 1/2" pelite polyethylene foam. Optional Aliplast (closed cell polyethylene) padding is available for the clear plastic bands.

The STARlight Cap design is made of the above plastic and contains no straps. The STARlight Side Opening design has a top opening and a side opening. The band is held in place by a Velcro strap across the side opening. The STARlight Bivalve design and the STARband Bi-Valve design consist of two plastic shells that overlap with a superior sliding mechanism. The right and left overlap tabs are connected via a Velcro strap with chafe and loop.

The proposed device modification is the addition of a new shape capture method, specifically the Ohio Willow Wood (OWW) Omega Scanner. Like the STARscanner Laser Data Acquisition system cleared with the STARlight (K021207 and K081994), the OWW Omega Scanner is a class 1 laser device. The OWW Omega Scanner is a handheld scanner consisting of two cameras, one laser, and eight LED lights.

V. Statement of Indications and Intended Use

Statement of Indications:

The STARlight is intended for medical purposes for use on infants from three to 18 months of age, with moderate to severe non-synostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic- and scaphocephalic-shaped heads by applying mild pressure to prominent regions of the infant's cranium in order to improve cranial symmetry and/or shape. The device is also indicated for adjunctive use for infants from three to eighteen months of age whose synostosis has been surgically corrected, but who still have moderate to severe cranial deformities including plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.

Intended Use:

The intended use is the same as it was for the STARlight in K081994; to correct head shape and proportion deformities. The STARlight is available by prescription only and is designed to treat infants with abnormal head shapes from age 3 to 18 months. Since growth is the driving factor in head shape correction, the infants wear the STARlight for approximately 23 hours per day. The most common head deformities are positional plagiocephaly, brachycephaly, and scaphocephaly. Recently the STARlight has also been cleared to treat unresolved head deformities in patients who have undergone surgery to correct craniosynostosis. The same principles of cranial remolding apply to positional deformities and post-operative patients.

VI. Summary of Technological Characteristics

The modification proposed is a change in how the infants head shape is captured; the technological characteristics and the underlying principles of operation of the STARlight cranial orthosis will remain exactly the same. This table illustrates that the device will in fact remain the same.

Table 1 – Comparison of Predicate Device cleared in K081994 to proposed device

Note: No changes will be made to the currently marketed device as a result of the proposed changes in this submission

Feature	From K081994	Proposed Device
Indications	The STARlight is intended for medical purposes for use on infants from three to 18 months of age, with moderate to severe non-synostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic- and scaphocephalic-shaped heads by applying mild pressure to prominent regions of the infant's cranium in order to improve cranial symmetry and/or shape. The device is also indicated for adjunctive use for infants from three to eighteen months of age whose synostosis has been surgically corrected, but who still have moderate to severe cranial deformities including plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.	The STARlight is intended for medical purposes for use on infants from three to 18 months of age, with moderate to severe non-synostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic- and scaphocephalic-shaped heads by applying mild pressure to prominent regions of the infant's cranium in order to improve cranial symmetry and/or shape. The device is also indicated for adjunctive use for infants from three to eighteen months of age whose synostosis has been surgically corrected, but who still have moderate to severe cranial deformities including plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.
Mechanism	Applies pressure to the prominent regions of the infants cranium in order to improve cranial symmetry and/or shape	Applies pressure to the prominent regions of the infants cranium in order to improve cranial symmetry and/or shape
Materials	Material for STARlight Side Opening, STARlight Bi-Valve, STARlight Cap - 5/32" - 1/4" clear Surlyn or 1/8" – 7/32" Clear Co-Polyester plastic shell Material for STARband Bivalve - Outer shell of 5/32" copolymer plastic - An inner liner of 1/2" pelite polyethylene foam Closure for Bivalve design - Sliding/Overlap closure system - Chicago screw (or similar) for top sliding mechanism - 1" velcro strap - 1" chafe buckle - 91X speedy rivets Closure for Side Opening design: - 1" Velcro Strap	Material for STARlight Side Opening, STARlight Bi-Valve, STARlight Cap - 5/32" - 1/4" clear Surlyn or 1/8" – 7/32" Clear Co-Polyester plastic shell Material for STARband Bivalve - Outer shell of 5/32" copolymer plastic - An inner liner of 1/2" pelite polyethylene foam Closure for Bivalve design - Sliding/Overlap closure system - Chicago screw (or similar) for top sliding mechanism - 1" velcro strap - 1" chafe buckle - 91X speedy rivets Closure for Side Opening design: - 1" Velcro Strap
Product Design	Custom made cranial orthosis, approx 7 to 10oz. in weight	Custom made cranial orthosis, approx 7 to 10oz. in weight

Production	- Form orthosis from a positive mold of infant's head - Positive mold is formed based upon measurements of the infant's head taken by the STARscanner from which a 3-dimensional image is made or from a traditional plaster cast - The 3-dimensional image is used to produce a positive mold using a 5-axis routing machine	- Form orthosis from a positive mold of infant's head - Positive mold is formed based upon measurements of the infant's head taken by the STARscanner or the OWW Omega Scanner from which a 3-dimensional image is made or from a traditional plaster cast - The 3-dimensional image is used to produce a positive mold using a 5-axis routing machine

The inclusion of the OWW Omega Scanner is the focus of this submission and that change is indicated in the table under the production section.

VII. Summary and Conclusions of Non-Clinical Performance Data

The OWW Omega Scanner was evaluated for safety and efficacy. The primary safety concern is the laser. The STARscanner and the OWW Omega Scanner are both class 1 laser devices and as such are inherently safe without eye protection under all normal operating conditions. The effectiveness of the OWW Omega Scanner was evaluated through accuracy, reproducibility, and repeatability testing. The OWW Omega Scanner met the predetermined acceptance criteria and was found safe and effective for use with Cranial Orthoses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Orthomerica Products, Inc.
% Mr. Alan T. Sandifer
Director of Research and Development
6333 North Orange Blossom Trail
Orlando, Florida 32810

OCT 31 2008

Re: K082945
Trade/Device Name: STARlight®
Regulation Number: 21 CFR 882.5970
Regulation Name: Cranial orthosis
Regulatory Class: II
Product Code: OAN, MVA
Dated: October 1, 2008
Received: October 2, 2008

Dear Mr. Sandifer:

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 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,

Mark N. Melkerson

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

Enclosure

Statement of Indications for Use

510K Number (if known): K082945

Device Name: STARlight®

Indications for Use:

The STARlight is intended for medical purposes for use on infants from three to 18 months of age, with moderate to severe non-synostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic- and scaphocephalic-shaped heads by applying mild pressure to prominent regions of the infant's cranium in order to improve cranial symmetry and/or shape. The device is also indicated for adjunctive use for infants from three to eighteen months of age whose synostosis has been surgically corrected, but who still have moderate to severe cranial deformities including plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.

Prescription Use _X_ 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)

Mark N Melkerson

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

510(k) Number K082945