SEP 1 2 2008

510(k) Summary

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 – July 11, 2008

II. Submission Information

- Type: Traditional 510(k) Submission
- Proprietary Name: STARlight
- Common Name: Cranial Orthosis
- Classification: Class II (special controls); OAN; 21 CFR 882.5970
- Classification Name: Cranial Orthosis
- Predicate Device: STARlight, Cranial Orthosis, K021207

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 the 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 original three devices from 510(k) K021207 are made of a plastic shell of 5/32" – 1/4" clear Surlyn or 1/8" - 7/32" Clear Co-Polyester. Since the original clearance a variation of the STARlight Bivalve has been released. It is identical in design to the STARlight Bivalve, but 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 its variation 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.

V. Statement of Indications for Use and Intended Use

Indications for Use:

The STARlight is intended for medical purposes for use in 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 STARlight is designed to treat infants with abnormal head shapes from age 3 months 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. However, due to new minimally invasive surgical techniques for infants with craniosynostosis, post-surgical plagiocephaly, brachycephaly, and scaphocephaly are emerging as a growing patient group.

Craniosynostosis is caused by the premature fusion of one or more cranial sutures of the skull, causing the head to grow into an unusual shape. Some types of craniosynostosis have a clinical presentation similar to deformational (positional) plagiocephaly. Therefore in cases where the physician cannot make a definitive diagnosis, patients are referred to specialists such as neurosurgeons or cranio-facial surgeons. These specialists will order a test like a CT scan or MRI to confirm the diagnosis of craniosynostosis. If a baby has craniosynostosis, surgery is indicated to realign the plates of the skull and allow normal brain and skull growth to occur.

In general, the first year of life is the optimum time frame for surgical correction since infants are growing at such an accelerated rate during that time. No matter which surgical technique is used, the end result is a patient with no fused sutures. At this point the same principles that guide cranial remolding of deformational head shapes are applicable. In both deformational head shapes and post-surgical head shapes the STARlight is designed to maintain total contact over areas where growth is not desired, and allow for space over areas where growth is desired. The STARlight provides a pathway for the baby's head growth, directing it toward a more normal shape.

VI. Summary of Technological Characteristics

As mentioned previously, minor changes that were determined not to require 510K submission have been implemented via Orthomerica's Engineering Change Order process. These changes are illustrated in the following table. Furthermore, there are no technological characteristics changes required for the expansion in indications requested within this 510(k) submission. Therefore this table may also serve as a comparison of the proposed device as compared to the predicate device.

Table 1

Comparison of Predicate Device cleared in 510(k) K021207 to the currently marketed device:
Note: No changes will be made to the currently marketed device as a result of the proposed indications change in this submission

Feature	510K Cleared Device	Currently Marketed Device
Intended Use	Maintains total contact over areas of bossing or protrusion and creates voids over areas of depression or flattening to redirect cranial growth toward greater symmetry.	Maintains total contact over areas of bossing or protrusion and creates voids over areas of depression or flattening to redirect cranial growth toward greater symmetry.
Materials	Material for all 3 designs: - 5/32" - 1/4" clear Surlyn or 1/8" – 7/32" Clear Co-Polyester plastic shell Closure for Bivalve design - Sliding/Overlap closure system - Chicago screw (or similar) for tope sliding mechanism - 1" velcro strap - 1" chafe buckle - 91X speedy rivets Closure for Side Opening design: - 1 ½" Velcro Strap - 1 ½" chafe buckle - 91X speedy rivet - Nylon washer (no closure for full form design – just plastic shell) Optional Cheek Pads - 1/8" Aliplast foam	Material for original 3 designs: - 5/32" - 1/4" clear Surlyn or 1/8" – 7/32" Clear Co-Polyester plastic shell Material for Bivalve variation - 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 tope sliding mechanism - 1" velcro strap - 1" chafe buckle - 91X speedy rivets Closure for Side Opening design: - 1" Velcro Strap (no closure for full form design – just plastic shell) Optional Cheek Pads - 1/8" Aliplast foam
Product Design	Custom made cranial remolding orthosis, approximately 7 to 10 ounces in weight, respective to the full form, side opening and bi-valved design.	Custom made cranial remolding orthosis, approximately 7 to 10 ounces in weight, respective to the full form, side opening and bi-valved design.
Production	Form orthosis from a positive mold of the infants head; positive mold is formed from a negative cast mold or three-dimensional scan of the infants head.	Form orthosis from a positive mold of the infants head; positive mold is formed from a negative cast mold or three-dimensional scan of the infants head.

The two changes indicated on the table are the introduction of the bivalve design variation and the strap change on the STARlight Side Opening Design. The bivalve design is a simple material change. The STARlight Side Opening strap design was improved to eliminate the possibility for the metal rivet to contact the patient's skin.

VII. Summary and Conclusions of Non-Clinical Performance Data

The STARlight cranial orthosis has been used successfully in clinical practice since its original clearance in 2002. The minor changes mentioned in the technical characteristics section above involved standard orthotic fabrication and materials that have undergone biocompatibility testing. However, the STARscanner™ Data Acquisition System used to capture the infant's head shape has had minor technical changes and with due diligence performance testing was conducted. The changes made to the STARscanner were to improve ease of use for the practitioner and to update components to the state of the art.

The accuracy, reproducibility, and repeatability of the STARscanner was evaluated by scanning three different cylindrical shapes(100mm, 125mm, 150mm diameters) five times at five different positions within the scan volume. Standard measurement systems statistical process control procedures were utilized to evaluate STARscanner errors, error standard deviations, repeatability of multiple scans, and reproducibility of multiple scans at multiple locations within the scan volume. The accuracy of the STARscanner II was confirmed to be better than the STARscanner I.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 2 2008

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

Re: K081994
Trade/Device Name: STARlight®
Regulation Number: 21 CFR 882.5970
Regulation Name: Cranial orthosis
Regulatory Class: II
Product Code: OAN, MVA
Dated: July 11, 2008
Received: July 14, 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
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): ~~unknown~~ K081994

Device Name: STARlight®

Indications for Use:

The STARlight is intended for medical purposes for use in 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)

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

510(k) Number K081994