510(k) Summary

K140353

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I. Applicant Information

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FDA Establishment Registration Number

1058152

Contact Information

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II. Submission Information

Type:	Traditional 510(k) Submission
Proprietary Name:	STARband® and STARlight®
Common Name:	Cranial Orthosis
Classification:	Class II (special controls); OAN; MVA; 21 CFR 882.5970
Classification Name:	Cranial Orthosis

III. Manufacturer Site

Name:	Orthomerica Products, Inc.
Address:	6333 North Orange Blossom Trail Orlando, FL 32810
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IV. Description of Device/Modification

The STARband and STARlight redirects the head growth to improve proportion and symmetry. The practitioner takes a plaster impression or 3-dimensional captured image of the infant's head to acquire the existing shape. The mold is sealed and filled with plaster or the 3-dimensional image 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 STARband and 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 further modified by the practitioner to provide space for growth to occur in the flat or depressed areas. The shape of the STARband and 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 STARband and STARlight product families as it was released in K124023 and K133250 are essentially still the same devices. The STARband Side Opening design and STARband Bi-Valve design is made with an outer shell of 5/32" polyethylene-polypropylene copolymer plastic with an inner liner made of 1/2" pelite polyethylene foam or 1/2" Aliplast foam (closed cell polyethylene). The STARlight Side Opening design and the STARlight Bi-Valve design are made of a plastic shell of 5/32" – 1/4" clear Surlyn or 1/8" - 7/32" Clear Co-Polyester. The STARlight PRO (Post-operative Remolding Orthosis) design is made of 1/4" to 3/8" clear Surlyn. Optional Aliplast (closed cell polyethylene) padding is available for the clear plastic bands and in addition, optional Reston (polyurethane – 3M Medical Product) foam is available for the STARlight PRO design.

The STARband Side Opening design and the STARlight Side Opening design has a top opening and a side opening. The band is held in place by a Velcro® strap (1 ½" for STARband Side Opening and 1" for STARlight Side Opening) across the side opening. The STARlight PRO has two side openings, no top opening, and is held in place by a Velcro strap across each side opening. The STARlight Bi-Valve 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 three new systems to use for 3-dimensional shape capture, specifically, the 3dMDhead™ System, the 3dMDcranial™ System and the 3dMDflex™ System all distributed by 3dMD, Inc. These systems use a non-coherent (i.e. non-laser light) structured light source and triangulated cameras to

capture shape data. Because these scanners utilize a non-coherent light source, they are safe to use on infant patients under all circumstances (equivalent to a Class 1 laser).

V. Statement of Indications and Intended Use

Statement of Indications:

The STARband and STARlight are intended for medical purposes for use on infants from 3 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 devices are also indicated for adjunctive use for infants from 3 to 18 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 STARband and STARlight are designed to treat infants with abnormal head shapes from age 3 to 18 months and is available by prescription only. Since growth is the driving factor in head shape correction, the infants wear the STARband or STARlight for approximately 23 hours per day. The most common head deformities are positional plagiocephaly, brachycephaly, and scaphocephaly. The STARband and STARlight have 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. Predicate Devices

- STARband, Cranial Orthosis, K124023
- STARlight, Cranial Orthosis, K133250
- Doc Band, K014012

VI. Summary of Technological Characteristics

The 3dMD Systems proposed in this 510(k) are additional methods to capture the infant's head shape for the fabrication of the STARband and STARlight Cranial Orthosis. The technological characteristics and the underlying principles of operation of the STARband and STARlight Cranial Orthosis shall remain exactly the same. The inclusion of the 3dMD Systems is the focus of this submission and that change is indicated in **Table 1** under the Approved 3-Dimensional Imaging Devices section.