



August 18, 2003

To Whom It May Concern:

The STARband Cranial Orthosis (K011350) was cleared for marketing on July 3, 2001, and manufactured by:

Orthomerica Products, Inc.
6333 North Orange Blossom Trail
Orlando, FL 32812

Indications for Use:

The STARband Cranial Orthosis is intended for medical purposes to apply 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- and brachycephalic-shaped heads. Orthomerica also intends to promote the use of the STARscanner as improving the accuracy, speed and convenience of the fabrication process as well as producing a reduction in the mental trauma to the infant and parents usually present in the manual casting process.

This device is not investigational.

I hope the information I've provided is helpful.

Sincerely yours,

Nancy M. Leonard
Public Health Advisor
Consumer Staff, HFZ-210
Division of Small Manufacturers,
International and Consumer Assistance
Office of Health and Industry Programs
Center for Devices and Radiological Health