



Ortho Pro prosthetics
orthotics
Ortho Pro Associates, Inc.

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November 15, 2006

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Docket # 2006P-0085
Rockville, Maryland 20852

Re: Docket # 2006P-0085 – Cranial Orthoses

Dear FDA Officials:

This letter is in response to the Federal Register notice published by the Food and Drug Administration on October 24, 2006. This notice requested comments on the possibility of establishing an exemption from the premarket notification requirements for cranial remolding orthoses (headbands). These devices are used to improve cranial symmetry for babies with plagiocephaly.

As a clinician very actively involved in the treatment of infants with deformational plagiocephaly, I strongly oppose this change. I sincerely believe that if cranial remolding orthoses are exempted from premarket notification requirements, it will create safety and effectiveness issues for babies that require cranial remolding orthoses. There are risks inherent in applying cranial orthoses to an infant's rapidly growing cranium, and it is ill advised to remove the current level of safeguards in place to protect this vulnerable population of patients.

We strongly agree with the FDA's determination on July 30, 1998 that cranial orthoses require regulation as Class II devices with special controls. This determination was made to provide reasonable assurance of safety of these devices. The FDA identified a number of health risks inherent in the use of these devices including the potential for skin breakdown, head and neck trauma, asphyxiation, eye trauma and impairments to brain growth and development.

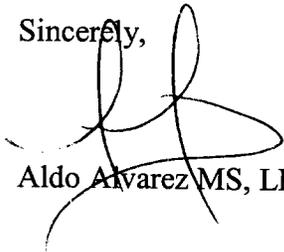
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The FDA revisited and reiterated this determination in a letter dated September 13, 2000. Although the FDA determined that cranial helmets used solely for protection are Class I devices, the FDA reaffirmed that cranial orthoses intended to improve cranial symmetry and/or shape will continue to be classified as Class II devices and will continue to require premarket notification.

It is very important that we ensure the utmost protection for babies with head shape anomalies by maintaining stringent regulation as presently mandated by the FDA.

Sincerely,



Aldo Alvarez MS, LPO



Terri Sparber Bukacheski LPOF