



## NOUVEAU PROSTHETICS AND ORTHOTICS

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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 – Cranial Orthoses**

Dear FDA Officials:

I am writing in response to the Federal Register notice published by the Food and Drug Administration on October 24, 2006. 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. These 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.

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,

Joseph Ghizzone, L.P.O.

2006P-0085

CS