

November 23, 2006

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket No. 2006P-0085

Dear Sirs:

I am writing in support of the petition to exempt cranial orthoses from premarket notification requirement. As you are aware, over the past 15 years, since the introduction of the Back to Sleep Campaign for the prevention of SIDS by the American Academy of Pediatrics, there has been a dramatic increase in the number of children with moderate to severe deformational plagiocephaly (positional molding). Over this time I have evaluated in excess of 4000 infants and recommended a cranial orthosis for the correction of a significant deformity resistant to conservative measures in approximately one third of these children. Among all of these patients treated with a cranial orthosis I have seen only one transient soft tissue injury without permanent scarring that occurred in a child being treated with the DOC band by a noncompliant parent. All of the other devices, both before the current FDA guidelines and after, manufactured by a variety of orthotic companies, have performed in a clinically identical fashion without any adverse clinical sequelae.

In my experience, the only difference in the utilization of cranial orthoses and their application since the institution of the Class II premarket notification requirements has been a dramatic increase in the cost of these devices resulting in additional financial burden to young families. Based on this extensive clinical experience as well as my knowledge of practice patterns among the pediatric neurosurgeons in this country, I do not believe that these devices present a risk for injury and thus should not have to meet the premarket Class II notification requirements. I would urge the committee to grant this petition.

Sincerely,

Jeffrey H. Wisoff, M.D.

Chairperson-Elect
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