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To: FDA

Re: FDA Docket 2006P-0085

Nobbe Orthopedics opposes the petition to exempt cranial orthoses from the premarket notification requirements that typically apply to Class II devices. We agree with the FDA determination of 7/30/1998 that these orthoses require special controls to ensure reasonable assurance of safety and effectiveness. At this time the FDA identified the following as potential health issues with cranial orthoses: skin breakdown, head and neck trauma, asphyxiation, eye trauma and impairments to brain growth and development.

On September 13, 2000 the FDA reaffirmed this decision. Cranial orthoses solely used for protection were determined to be Class I devices. Orthoses intended to improve skull shape continued to be classified as Class II, requiring premarket notification. Health risks associated with use of cranial orthoses for the modification of infant skull shapes have not changed significantly. Treatment of this vulnerable population must be regulated.

The Petitioner did not provide any meaningful evidence that suggests ongoing innovation, development or patient access have been impeded by the Class II designation. In fact, patient access to a superior orthoses and associated therapy has increased. The Petitioner states that cranial orthoses are manufactured by "large national conglomerates." The FDA website states that 28 510(k)s for various cranial orthoses have been cleared since 1998. Independent orthotic and prosthetic providers are the clear majority. The FDA website shows 510 (k)s have been secured by 10 orthotists, 6 hospitals, and 6 manufactures. The Petitioner also indicates that price increases have been impacted by the FDA's regulation. The primary cause of increase is in the service intensity associated with this treatment modality. Cranial orthoses involve weekly followed by bi-monthly clinical visits by the treating orthotist. Cranial orthoses are billed under HCPCS Level II codes, cost of clinical visits must be bundled together with the cost of the orthoses.

We believe the Petitioner's request fails to meet the criteria used for determination under Section 510(m)(2) of the FDAMA. We strongly support the FDA's current position! We urge the FDA to refrain from removing the existing premarket notification requirements for cranial orthoses.

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