



# Children's Hospital Boston

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The Christopher K. Fellows Family Chair in Pediatric Neurosurgery

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# HARVARD MEDICAL SCHOOL

Department of Surgery  
Professor of Surgery

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Division of Dockets Management (HFA 305) Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852  
[www.fda.gov/doc/ecomments](http://www.fda.gov/doc/ecomments)

RE: docket # 2006P-0085

To Whom It May Concern:

I am writing regarding the above-captioned petition to exempt cranial orthoses from pre-market notification requirements. I am a pediatric neurosurgeon who is currently the Neurosurgeon-in-Chief at the Children's Hospital, Boston. I am a past member and Vice Chairman of the American Board of Neurological Surgery, the current Chairman of the American Board of Pediatric Neurologic Surgery, a past chairman of the Pediatric Section of the American Association of Neurologic Surgeons, and a current member of its executive committee. I have been a practicing neurosurgeon specializing in pediatric neurosurgery for more than thirty years, and believe I have a good vantage point from which to comment on this proposed exemption.

There is a long history of the use of cranial orthoses to passively mold malformations of the infant skull. We have been using these devices as made in our hospital brace shops for decades. The materials that these molding helmets and orthoses are composed are synthetic materials that are commonly used for bracing the extremities in the treatment of sprains and fractures, including the Velcro straps that secure the cranial orthosis to the infant's head. These are all approved materials and I believe that their long-term usage in many clinical settings by experienced pediatric neurosurgical practitioners bears evidence to their safety and long term efficacy. My colleagues and I at the Children's Hospital, Boston and throughout the country feel that these devices should be exempt from pre-market class II notification requirements, although they will continue to be available only by prescription with correct labeling. I will be happy to comment further on this issue should the Dockets Management branch require additional information.

Sincerely,

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