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Department of Health and Human Services

To: FDA  
From: Dr. Joseph Boyle, President, Orthotics Choice, LLC

RE: **Docket #2006P-0085**  
Medical Devices, Exemptions from pre-market notification, class I devices

Dear Heather S. Rosecrans,

This letter is intended to suggest to the FDA that cranial shaping helmets could easily be classified as a Class I device. Our company has over 30 years of combined experience, and we realize that the procedures to thermoform and modify the plastic, and then strap these helmets is basically the same as most class 1 devices. Those who would tell you differently are only doing so to protect their financial interest. If the pre-market approval is removed, it will provide easier access to the helmets, and lower the price. Both which are a benefit to the patients and the current health care system.

Our current field of Neurologists and Orthotists are more that qualified to protect the patient from defective helmets. With this type of medical condition, time is of the essence and removing the 510k pre-market notification process will provide a quicker time frame in which the helmet can be given to the patient. Moreover it will also make all manufactures of shaping helmets improve their quality, price and efficiently.

Thank you for your time and cooperation in this matter. If I can be of any further assistance please feel free to contact me at 407-321-0454.

Sincerely,



Dr. Joseph Boyle

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