



Childrens Hospital Los Angeles

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November 27, 2006

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

RE: Docket #2006P-0085 Medical Devices; Exemption from pre-market notification; Class 2 devices.

On November 15, 2006, you received a letter from Kevin N. Bitting and Sylverie Valentin. Their letter was in support of denying exemptions from pre-market notification for cranial orthoses. Included in the documents was a letter from our fellow, Ramin J. Javahery, M.D, that included both my name and that of Dr. Mark Krieger. This states that, in our experience, the DOC Band was superior to the STAR band in terms of correcting positional plagiocephaly. While we agree with the statements in the letter, our name was used without any prior consultation. The inference is that we support the position of Bitting and Valentin that cranial orthoses should not be exempt from pre-market notification. We have taken no position on this matter.

We have seen infants whose treatment with molding cranial orthotic devices has not been optimal. Whether it is the molding device or the application of the device that results in less than optimal outcome is unknown to us. It is clear that both components are required. Our goal has always been to provide the best care for our patients. If the outcome is equal, we would definitely advocate the device that is less expensive.

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cc: Divisions of Dockets Management (HFA-305)
Mark R. Proctor, M.D.

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