



November 20, 2006

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Docket # 2006P-0085  
Rockville, Maryland 20852

**Re: Docket # 2006P-0085 – Cranial Orthoses**

Dear FDA Officials:

I am writing in response to the Federal Register notice published by the Food and Drug Administration on October 24, 2006. This notice requested comments on the possibility of establishing an exemption from the premarket notification requirements for cranial remolding orthoses (headbands). These devices are used to improve cranial symmetry for babies with plagiocephaly.

As a clinician very actively involved in the treatment of infants with deformational plagiocephaly, I strongly oppose this change. I sincerely believe that if cranial remolding orthoses are exempted from premarket notification requirements, it will create safety and effectiveness issues for babies that require cranial remolding orthoses. There are risks inherent in applying cranial orthoses to an infant's rapidly growing cranium, and it is ill-advised to remove the current level of safeguards in place to protect this vulnerable population of patients.

It is very important that we ensure the utmost protection for babies with head shape anomalies by maintaining stringent regulation as presently mandated by the FDA.

Sincerely,



Nicholas C. Perrow, CPO  
Plattner Orthopedic Company

**2006P-0085**

**C10**

311 West R.B. Garrett Avenue • Peoria, Illinois 61605  
Phone: 309-682-1382 • 800-551-4276 • Fax: 309-682-7125  
[www.plattners.com](http://www.plattners.com)



1863 6 2006 11:01

November 20, 2006

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Docket # 2006P-0085  
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Sincerely,

Craig A. Plattner, CO, FAAOP  
Plattner Orthopedic Company  
President

311 West R.B. Garrett Avenue • Peoria, Illinois 61605  
Phone: 309-682-1382 • 800-551-4276 • Fax: 309-682-7125  
[www.plattners.com](http://www.plattners.com)

UNIVERSITY OF  
**ROCHESTER**  
MEDICAL CENTER

DEPARTMENT OF ORTHOTICS AND PROSTHETICS

November 21, 2006

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Docket # 2006P-0085  
Rockville, Maryland 20852

1864-6 NOV 24 P1:22

Re: **Docket # 2006P-0085 – Cranial Orthoses**

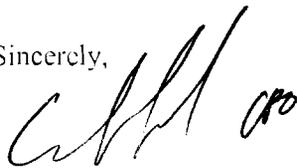
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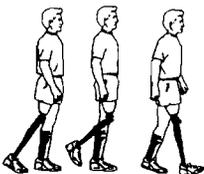
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Sincerely,



Eric Shoemaker, CPO  
Certified Prosthetist and Orthotist  
Residency Coordinator



601 Elmwood Avenue, Box 625  
Rochester, New York 14642  
(716) 275-3331



1866 6 NOV 24 P1:24

November 21, 2006

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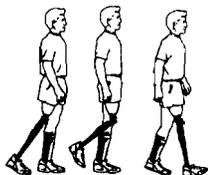
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Sincerely,



Robert Brown, MS, CPO, FAAOP  
Chief of Orthotics and Prosthetics  
Assistant Professor – Department of Orthopaedics



1867 6 NOV 24 P1:24

November 21, 2006

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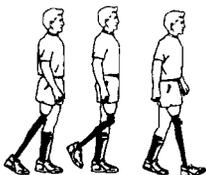
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Sincerely,



Mary Kate Gedro, CO  
Certified Orthotist  
Clinical Coordinator



1868 6 NOV 24 11:24

November 21, 2006

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane Room 1061  
Docket # 2006P-0085  
Rockville, Maryland 20852

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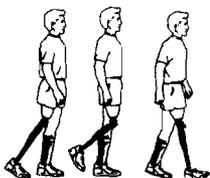
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Sincerely,



Chase Brown, CPO  
Certified Prosthetist and Orthotist



Date: 11/20/06

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5630 Fishers Lane, Room 1061  
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Sincerely,



Kathlyn A. Brumfield, OTR



ORTHOTICS & PROSTHETICS, INC.

**Kearny Mesa Office**

7720 Cardinal Court  
San Diego, CA 92123  
Phone: (858) 292-7448  
Fax: (858) 292-0927

**South Bay Office**

340 Fourth Ave. Ste. 14  
Chula Vista, CA 91910  
Phone: (619) 585-8421  
Fax: (619) 585-8874

**North County Office**

475 N. Grape Street  
Escondido, CA 92025  
Phone: (760) 489-0533  
Fax: (760) 489-0428

**La Jolla Office**

4150 Regents Park Row, Ste. 265  
La Jolla, CA 92037  
Phone: (858) 453-1933  
Fax: (858) 453-1813

**East County Office**

8875 La Mesa Blvd., Ste. B  
La Mesa, CA 91941  
Phone: (619) 589-9980  
Fax: (619) 589-9988

**Tri-City Office**

1929 W Vista Way, Ste. A  
Vista, CA 92083  
Phone: (760) 941-1323  
Fax: (760) 941-6452

**Mission Viejo Office**

26440 La Alameda, Ste. 320  
Mission Viejo, CA 92691  
Phone: (714) 367-6600  
Fax: (949) 367-6617

**Imperial Valley Office**

1600 S. Imperial Ave., Ste 15  
El Centro, CA 92243  
Phone: (760) 336-0333  
Fax: (760) 336-2333

**Children's Hospital**

8008 Frost St. STE. 407  
San Diego, CA 92123  
Phone: (858) 560-0660  
Fax: (858) 560-0870

**Orange County Office**

1920 E. Katella, Ste. G,H,I  
Orange, CA 92867  
Phone: (714) 639-7422  
Fax: (714) 639-8990

**Laguna Woods Office**

24331 El Toro Rd., Ste 335  
Laguna Woods, CA 92637  
Phone: (949) 583-9667  
Fax: (949) 583-9906

**Central Fabrication,  
Purchasing/Stockroom**

7571 Convoy Court  
San Diego, CA 92111  
Lab Phone: (858) 292-6045  
S/R Phone: (858) 569-3800  
Fax: (858) 569-3803

**Cast Rooms:**

**California Ortho. Institute**  
7485 Mission Valley Road, Ste 104  
San Diego, CA 92108

**UCSD Orthomed**  
4150 Regents Park Rows, Ste. 300  
La Jolla, CA 92037

Date: 11-21-06

Division of Dockets Management (HFA-305)

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5630 Fishers Lane, Room 1061

Docket # 2006P-0085

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NOV 27 11:39 AM '06

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I am writing in response to the Federal Register notice published by the Food and Drug Administration on October 24, 2006. This notice requested comments on the possibility of establishing an exemption from the pre-market notification requirements for cranial remolding orthoses. These devices are used to improve cranial symmetry for babies with plagiocephaly, brachycephaly and scaphocephaly.

As a clinician very actively involved in the treatment of infants with deformational asymmetries (our office fits between 15-25 helmets a month), I strongly oppose this change. I believe that if cranial remolding orthoses are exempted from pre-market notification requirements, it will create safety and effectiveness issues for babies that require cranial remolding orthoses. There are risks inherent in applying cranial orthoses to an infant's rapidly growing skull, and it is ill-advised to remove the current level of safeguards in place to protect this vulnerable population of patients.

It is very important that we ensure the utmost protection for babies with head shape anomalies by maintaining stringent regulation as presently mandated by the FDA.

Sincerely,

Ellie Boomer, CPO  
SCOPE Orthotics & Prosthetics, Inc.  
Children's Office  
8008 Frost St., Suite 407  
San Diego, CA 92123  
858-560-0660