



November 15, 2006

CERTIFIED AND REGULAR US MAIL

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

RE: Docket No. 2006P-0085 Medical Devices; Exemptions from Premarket Notification; Class II Devices

To Whom It May Concern:

Please find enclosed a copy of FDA Docket No. 2006P-0085 as well as notification from the American Orthotic & Prosthetic Association (AOPA) regarding the American Association of Neurological Surgeons, the Congress of Neurological Surgeons (AANS/CNS), and the AANS/CNS Section on Pediatrics filed petition requesting an exemption from premarket notification for cranial orthoses.

Current industry standards in training and education for infant cranial remodeling have only recently started to become more cohesive during the past 6 years (2000-2006) with the advent of more device manufacturers; however, an inexperienced clinician can negate any device's known performance or design.

Our center has treated infants for over 15 years coordinating with pediatricians, pediatric neurological, craniofacial and orthopedic surgeons. During the early 1990s, less than a handful of orthotists nationwide were actually treating infant deformities. We have seen first hand the results stemming from inexperienced and unqualified clinicians during those early years and presently continue to do so [*see enclosed*]. Now the FDA is petitioned to increase this clinical probability by relaxing its standards in premarket notification(s).

The scientific principle(s) used in quantifying infant cranial deformities are not uniformly adhered to within the medical community, yet valid and exacting science demands it. The standards for measuring the skull and face, in all primates-modern man included, have existed for many decades.¹⁻¹⁰ Some of these measurements have been utilized for over a century of which *modern* anthropometric protocol is based.¹¹⁻¹³ Evidence based outcomes for cranial orthoses begins with anthropometry, which continues to be a currently recognized standard in quantifying skull morphology in medicine and research.¹⁴⁻¹⁶ Nationwide, insurance carriers reference anthropometric measurements in establishing treatment and benefit criteria; however, we believe their normative values are based upon limited studies conducted with a smaller number of subjects.¹⁷⁻¹⁹

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3-D imaging and CAD-CAM technologies are capable of illustrating volumetric changes that occur in infant cranial remodeling, an extremely useful clinical tool; however, current challenges in computer modeling and quantification lie in accurate and uniform skull landmark identification.²⁰ This is why many anthropologists worldwide still use human observation and subsequent (caliper) calibration when measuring live and dried skulls. Hopefully, an algorithm that superimposes both computer modeling and accurate anthropometric landmark identification will eventually be perfected while remaining truly cost effective for widespread clinical use.²¹⁻²⁶

Neonates requiring non-surgical and postoperative correction of the cranium are the most vulnerable patient treatment population. Both treatment protocols and "quantification of outcomes" remain vague to the majority of those practitioners who actually treat infants compromising both validation of a device's effectiveness and clinical outcomes.

We believe that the FDA and relevant medical certification specialties should actually move toward even more stringent requirements by requiring separate clinical certification(s) specific to infant cranial orthotics along with a standard of medical care, which must include homogeneous quantification. Having a (general) certification in orthotics or medicine and purchasing a cranial orthotic from a device manufacturer is insufficient criteria for public safety and treatment effectiveness, regardless of any assurances through licensure or current device approval by the FDA.

There are two sides to this equation: exceptional cranial orthotic design and extensive clinical experience with scientifically accepted measurement protocols. Exemption of cranial orthoses from pre-market notification affects the entire equation. This exemption will allow the potential for inferior and possibly dangerous design(s) in cranial orthotic manufacturing, non-scientifically recognized quantification(s) of pre- and post-treatment, as well as encouraging inexperienced clinicians access to this most at-risk population.

Sincerely,



Kevin N. Bitting, BOC, CO
Pediatric Craniofacial Orthotist
Cranial Therapies, Inc.



Sylvere Valentin
Clinical Anthropologist
Cranial Therapies, Inc.

KNB/SV:mda
Enclosure

- c American Association of Neurological Surgeons/Congress of Neurological Surgeons (AANS/CNS)
- American Orthotic Prosthetic Association (AOPA)
- American Academy of Orthotist and Prosthetists (AAOP)
- American Board for Certification in Orthotics and Prosthetics, Inc. (ABC)
- Board for Orthotist/Prosthetist Certification (BOC)

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