

U.S. FDA Regulation of Orthotic Treatment of Deformational Plagiocephaly

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INTRODUCTION

Orthotic treatment of deformational plagiocephaly has become a common practice in the United States. As this new "industry" emerged, it was unclear as to how these devices would be regulated by the U.S. Food and Drug Administration (FDA). In this presentation, we will share with you information regarding the concerns raised by the FDA, the final ruling on the classification of these devices, as well as summarize the studies submitted to demonstrate the safety and effectiveness of our orthotic treatment program.

REGULATION

Although orthotic treatment of deformational plagiocephaly can be traced as far back as 1979(1), for many years it has been erroneously believed that these devices were exempt from federal regulation. However, in 1995 our office was contacted by the FDA, and informed that this was not the case, and that our device would require submission of a premarket notification [510(k)]. In a 510(k) application, a manufacturer demonstrates that their device is "Substantially Equivalent" (SE) to other devices, known as predicate devices, already cleared for market. Since no device had ever been cleared by the FDA for treatment of deformational plagiocephaly, there were no predicate devices to claim equivalence to, and hence the application was rejected.

Under new legislation passed in the 1997 FDA Modernization Act (FDAMA), a new pe-

tion was submitted under section 207, which allows a risk-based classification of inherently low risk medical devices for which no predicate is available. In this petition, as well as numerous correspondences between the FDA and our organization, information was submitted which demonstrated the safety and effectiveness of our device. (2)

To demonstrate the efficacy of our orthosis, we submitted the results of numerous clinical investigations previously published in the medical literature.(3-6) In these studies, we were able to demonstrate a statistically significant reduction of craniofacial asymmetry, as well as the stability of this correction once an infant left treatment.

The FDA response to our submission was a request for additional information, this time asking us to establish the appropriate ages for treatment, and clarifying why infants should be treated prior to one year of age. In response, a study was completed that demonstrated that earlier intervention results in significantly improved outcomes, independent of the severity of the presenting condition.(7) This quantitative assessment was further validated by numerous citations in the medical literature in which similar clinical observations had been made.

Once able to demonstrate our ability to redirect symmetrical growth, concerns were raised about potential developmental impairment resulting from the restrictions placed on the cranium. A study was submitted whose findings demonstrated that treatment resulted in statistically significant reductions in craniofacial asymmetry, while more importantly documenting that this correction was achieved with concomitant, statistically significant growth of the skull.(8) Moreover, it was also demonstrated that treated infants exhibited normal growth trajectories when compared against age- and gender-specific norms.

Information was also requested about the incidence of skin irritation and breakdown associated with use of these devices. Review of our database indicated that skin irritation had occurred in 6.8% of the cases while skin breakdown was reported in 4.2% of the cases. However, it was also demonstrated that in each instance, the irritation or breakdown had been resolved by following our written clinical procedures.

Subsequent biocompatibility testing of the materials used for sensitization, skin irritation, and cytotoxicity were also required.

Table 1: FDA Required General and Special Controls

GENERAL CONTROLS	
(1)	Registration of Establishment with the FDA
(2)	Listing of the Device Manufactured with the FDA
(3)	Submission of a PreMarket Notification [510(k)]
(4)	Manufacturing under the FDA's Quality System (QS) Guidelines
SPECIAL CONTROLS	
(1)	Restricted to Prescription Use (21 CFR 01.109)
(2)	Labeling Requirements Specifying:
(a)	<i>Contraindications</i> for use with synostosis or hydrocephalus
(b)	<i>Warnings</i> indicating need to evaluate growth and development, steps to be taken to reduce the potential for restriction of growth, and the need to monitor skin for irritation and breakdown and steps to be taken if this occurs.
(c)	<i>Precautions</i> indicating the need to: treat torticollis, frequently evaluate device fit, and evaluate structural integrity of device.
(d)	<i>Adverse Events</i> indicating that skin irritation and breakdown have occurred with use of this device.
(e)	<i>Clinical Instructions</i> for casting the infant, fitting the device, and care.
(f)	<i>Parental Instructions</i> for Wear & Care of device.
(3)	Biocompatibility Testing of materials used for Sensitization, Skin Irritation, and Cytotoxicity.

RESULTS

On May 29th, 1998 the FDA made a final ruling classifying cranial orthotics used for the treatment of deformational plagiocephaly as Class II, Neurology devices.

"The device is assigned the generic name 'cranial orthosis', and is identified as a device intended for use on infants from 3 to 18 months of age with moderate to severe nonsynostotic, positional plagiocephaly, including infants with plagiocephalic-, brachycephalic-, and scaphocephalic- shaped heads. The device is intended for medical purposes to apply pressure to the prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape." (9).

The FDA determined that both general and special controls were required to ensure the safety and effectiveness of these devices (Table

1). Additionally, the potential health risks that may be associated with these devices were also identified (Table 2).

CONCLUSIONS

The purpose of this presentation has been to share our experience regarding federal regulation of cranial orthotics, as well as identify the concerns raised about this form of treatment. To summarize, these devices are in fact regulated by the U.S. Food and Drug Administration, and are classified as Class II Neurology Devices (21 CFR 882.5970). The Class II designation demonstrates that the FDA had significant concerns about the safety of these devices if not used appropriately. Consequently, the FDA identified special controls required to ensure the safe and effective use, and requires submis-

Table 2: Potential Health Risks Associated with Cranial Orthotics

POTENTIAL HEALTH RISKS	
(1)	Skin irritation, skin breakdown and subsequent infection due to excessive pressure on the skin
(2)	Head and neck trauma due to alteration of the functional center of mass of the head and the additional weight of the device especially with an infant who is still developing the ability to control his/her head and neck movements.
(3)	Impairment of brain growth and development from mechanical restriction of growth.
(4)	Asphyxiation due to mechanical failure, poor fit, and /or excessive weight that alters the infant's ability to lift the head.
(5)	Eye trauma due to mechanical failure, poor construction and /or inappropriate fit.
(6)	Contact dermatitis due to the materials used in the construction of the device.

sion of a 510(k) prior to placing these devices on the market.

DISCLOSURE

Mr. Littlefield is the Director of R&D for Cranial Technologies, Inc.

REFERENCES

1. CLARREN SK, SMITH DW, HANSON JW: *Helmet treatment for plagiocephaly and congenital muscular torticollis*. J Pediatr 94: 43-46, 1979.
2. DUNNING HN, LITTLEFIELD TR. *Section 207: Is your Class III designation really final?* Medical Device and Diagnostic Industry. January: 117-123, 1999
3. RIPLEY CE, POMATTO JK, BEALS SP, JOGANIC EF, MANWARING KH, MOSS SD: *Treatment of positional plagiocephaly with Dynamic Orthotic Cranioplasty*. J Craniofac Surg 5:150-159, 1994.
4. JOGANIC EF, BEALS SP, RIPLEY CE, POMATTO JK, MANWARING KH, MOSS SD. *Enhancement of craniofacial reconstructions by dynamic orthotic cranioplasty*. In Marchac ed, Craniofacial Surgery V: Proceedings of the fifth international congress of the international society of craniofacial surgery. Bologna, Italy, Monduzzi Editore 1995.
5. LITTLEFIELD TR, BEALS SP, MANWARING KH, POMATTO JK, JOGANIC EF, GOLDEN KA, RIPLEY CE. *Treatment of craniofacial asymmetry with dynamic orthotic cranioplasty*. J Craniofac Surg. 9: 11-17, 1998.
6. LITTLEFIELD TR, POMATTO JK, BEALS SP, JOGANIC EF, MANWARING KM, RIPLEY CE. *Efficacy and stability of dynamic orthotic cranioplasty: an eight year investigation*. In Whitaker ed, Craniofacial Surgery VII: Proceedings of the seventh international congress of the international society of craniofacial surgery. Bologna, Italy, Monduzzi Editore 1997.
7. KELLY KM, LITTLEFIELD TR, POMATTO JK, RIPLEY CE, BEALS SP, JOGANIC EF. *Importance of early recognition and treatment of deformational plagiocephaly with orthotic cranioplasty*. Cleft Palate Craniofac J 36: 127-130, 1999.
8. KELLY KM, LITTLEFIELD TR, POMATTO JK, MANWARING KM, BEALS SP. *Cranial growth unrestricted during treatment of deformational plagiocephaly*. Pediatr Neurosurg 30: 193-199, 1999.
9. Federal Register, 63 FR: 40650-40652, July 30, 1998.