

**K063098 STATIC CRANIOPLASTY ORTHOSIS**Apr 11, 2007  
183 days to decisionK063098 · Product code: **OAN** · Neurology  
Source: <https://www.510kdatabase.net/k063098/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Cranial, Laser Scan (OAN)
Date received	Oct 10, 2006
Decision date	Apr 11, 2007
Days to decision	183 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Boston Brace Intl., Inc.</b>
Location	Avon, MA, US
Contact	JAMES WYNNE
510(k) history	3 submissions · 3 cleared · 2007-2011

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