

K081787 CAMLAB CRANIAL ORTHOSIS HELMETJan 27, 2009
217 days to decisionK081787 · Product code: **OAN** · Neurology
Source: <https://www.510kdatabase.net/k081787/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Cranial, Laser Scan (OAN)
Date received	Jun 24, 2008
Decision date	Jan 27, 2009
Days to decision	217 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biosculptor Corporation
Location	Hialeah, FL, US
Contact	MARK MAZLOFF
510(k) history	1 submissions · 1 cleared · 2009-2009

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