

K111310 BRUX MOUTHGUARDSDec 8, 2011
212 days to decisionK111310 · Product code: **OBR** · Dental
Source: <https://www.510kdatabase.net/k111310/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Over-the-counter (OBR)
Date received	May 10, 2011
Decision date	Dec 8, 2011
Days to decision	212 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dental Arte, Inc.
Location	Poway, CA, US
Contact	CAROLYN PRIMUS
510(k) history	2 submissions · 2 cleared · 2006-2011

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