

K083400 CUSTOM COMFORT NIGHTGUARDDec 11, 2008
24 days to decisionK083400 · Product code: **OBR** · Dental
Source: <https://www.510kdatabase.net/k083400/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mouthguard, Over-the-counter (OBR)
Date received	Nov 17, 2008
Decision date	Dec 11, 2008
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Den Tek Oral Care, Inc.
Location	Washington, Dc, DC, US
Contact	HOWARD M HOLSTEIN
510(k) history	8 submissions · 8 cleared · 2007-2015

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