

**K091660 CUSTOM COMFORT NIGHTGUARD VERSION 2**Jun 12, 2009  
3 days to decisionK091660 · Product code: **OBR** · Dental  
Source: <https://www.510kdatabase.net/k091660/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mouthguard, Over-the-counter (OBR)
Date received	Jun 9, 2009
Decision date	Jun 12, 2009
Days to decision	3 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k091660/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 3, 2026