

**K180933 DenTek Ultimate Dental Guard**Sep 17, 2018  
160 days to decisionK180933 · Product code: **OBR** · Dental  
Source: <https://www.510kdatabase.net/k180933/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Over-the-counter (OBR)
Date received	Apr 10, 2018
Decision date	Sep 17, 2018
Days to decision	160 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medtech Products, Inc.</b>
Location	Miami, FL, US
Contact	Mary Beth Fritz
510(k) history	9 submissions · 9 cleared · 1985-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k180933/> 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 May 26, 2026