

**K151933 BRX PRO Bruxism Guard**Dec 10, 2015  
149 days to decisionK151933 · Product code: **MQC** · Dental  
Source: <https://www.510kdatabase.net/k151933/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Prescription (MQC)
Date received	Jul 14, 2015
Decision date	Dec 10, 2015
Days to decision	149 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>12th Man Technologies, Inc.</b>
Location	Garden Grove, CA, US
Contact	ALEX STENZLER
510(k) history	2 submissions · 2 cleared · 2015-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k151933/> 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