

**K123161 SMARTGUARD NIGHT GUARD, SMARTGUARD ORIGINAL, SMARTGUARD NIGHT GUARD ORIGINAL, SMARTGUARD ELITE**Mar 14, 2013  
156 days to decisionK123161 · Product code: **MQC** · Dental  
Source: <https://www.510kdatabase.net/k123161/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Prescription (MQC)
Date received	Oct 9, 2012
Decision date	Mar 14, 2013
Days to decision	156 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Smartguard, Inc.</b>
Location	Miami, FL, US
Contact	SHELLY GARG
510(k) history	1 submissions · 1 cleared · 2013-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k123161/>. 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 9, 2026