

**K110468 FREEWAY COMFORT BITE GUARD**Aug 5, 2011  
169 days to decisionK110468 · Product code: **MQC** · Dental  
Source: <https://www.510kdatabase.net/k110468/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Prescription (MQC)
Date received	Feb 17, 2011
Decision date	Aug 5, 2011
Days to decision	169 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Randmark Dental Products, LLC</b>
Location	Potomac, MD, US
Contact	NORMAN F ESTRIN
510(k) history	1 submissions · 1 cleared · 2011-2011

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