

K121365 THERMOFORMED MOUTHGUARDSNov 20, 2012
197 days to decisionK121365 · Product code: **MQC** · Dental
Source: <https://www.510kdatabase.net/k121365/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Prescription (MQC)
Date received	May 7, 2012
Decision date	Nov 20, 2012
Days to decision	197 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Glidewell Laboratories-Sleep Devices Group
Location	Irvine, CA, US
Contact	ARMIN ZEHTABCHI
510(k) history	1 submissions · 1 cleared · 2012-2012

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