

**K112868 DREAMGARD REM-SOFT, DREAMGARD REM-LITE,
DREAMGARD REM-ULTRA, DREAMGARD REM-MAX**

Jan 19, 2012
111 days to decision

K112868 · Product code: **MQC** · Dental
Source: <https://www.510kdatabase.net/k112868/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Prescription (MQC)
Date received	Sep 30, 2011
Decision date	Jan 19, 2012
Days to decision	111 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dreamgard, Inc.
Location	Washington, DC, US
Contact	SUZAN ONEL
510(k) history	1 submissions · 1 cleared · 2012-2012

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k112868/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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