

**K143623 Narval Brux**Aug 13, 2015  
234 days to decisionK143623 · Product code: **MQC** · Dental  
Source: <https://www.510kdatabase.net/k143623/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Prescription (MQC)
Date received	Dec 22, 2014
Decision date	Aug 13, 2015
Days to decision	234 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Resmed Sas</b>
Location	San Diego, CA, US
Contact	Larissa D&apos;Andrea
510(k) history	2 submissions · 2 cleared · 2011-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k143623/> 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 4, 2026