

**K181099 Bright Guard**Jan 18, 2019  
267 days to decisionK181099 · Product code: **OBR** · Dental  
Source: <https://www.510kdatabase.net/k181099/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Over-the-counter (OBR)
Date received	Apr 26, 2018
Decision date	Jan 18, 2019
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Koncept Innovators, LLC</b>
Location	Myrtle Beach, SC, US
Contact	Sylvan Newby
510(k) history	2 submissions · 2 cleared · 2019-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Newworld Regulatory Solutions, Inc.</b>
Contact	Maureen Garner

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181099/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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