

K181361 Brux Night GuardApr 11, 2019
323 days to decisionK181361 · Product code: **MQC** · Dental
Source: <https://www.510kdatabase.net/k181361/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Prescription (MQC)
Date received	May 23, 2018
Decision date	Apr 11, 2019
Days to decision	323 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Brux Night Guard
Location	Canoga Park, CA, US
Contact	John Scalco
510(k) history	1 submissions · 1 cleared · 2019-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181361/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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