

K182820 The PODJul 17, 2019
286 days to decisionK182820 · Product code: **MQC** · Dental
Source: <https://www.510kdatabase.net/k182820/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mouthguard, Prescription (MQC)
Date received	Oct 4, 2018
Decision date	Jul 17, 2019
Days to decision	286 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Advanced Facialdotics, LLC
Location	St James, NY, US
Contact	Scott Simonetti
510(k) history	2 submissions · 2 cleared · 2019-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182820/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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