

K182826 Ormco Spark Aligner SystemOct 11, 2018
6 days to decisionK182826 · Product code: **NXC** · Dental
Source: <https://www.510kdatabase.net/k182826/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Oct 5, 2018
Decision date	Oct 11, 2018
Days to decision	6 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sybron Dental Specialties
Location	Newport Beach, CA, US
Contact	Mey Saied
510(k) history	15 submissions · 15 cleared · 2006-2018

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Mark Job

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182826/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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