

K180346 Byte Aligner SystemFeb 19, 2019
376 days to decisionK180346 · Product code: **NXC** · Dental
Source: <https://www.510kdatabase.net/k180346/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Feb 8, 2018
Decision date	Feb 19, 2019
Days to decision	376 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Straight Smile, LLC
Location	Pacific Palisades, CA, US
Contact	Sepi Abbasi
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Coombs Medical Device Consulting, Inc.
Contact	Craig Coombs

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180346/> Data sourced from FDA 510(k) public records (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. - Generated June 28, 2026