

K183643 Clear Image AlignersJan 3, 2019
8 days to decisionK183643 · Product code: **NXC** · Dental
Source: <https://www.510kdatabase.net/k183643/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Dec 26, 2018
Decision date	Jan 3, 2019
Days to decision	8 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Specialty Appliance Works, Inc.
Location	Marietta, GA, US
Contact	Carolyn Thomas
510(k) history	3 submissions · 3 cleared · 2007-2019

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

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Device record: <https://www.510kdatabase.net/k183643/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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