

K192470 DenMat Orthodontic AlignersDec 20, 2019
102 days to decisionK192470 · Product code: **NXC** · Dental
Source: <https://www.510kdatabase.net/k192470/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Sep 9, 2019
Decision date	Dec 20, 2019
Days to decision	102 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Denmat Holdings, LLC
Location	Lompoc, CA, US
Contact	Tom Juarez
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

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

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