

K192069 Aerodentis SystemMay 6, 2020
279 days to decisionK192069 · Product code: **NXC** · Dental
Source: <https://www.510kdatabase.net/k192069/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Aug 1, 2019
Decision date	May 6, 2020
Days to decision	279 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dror Orthodesign
Location	Jerusalem, IL
Contact	Michael Nadav
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Hogan Lovelle US Llp
Contact	Janice M. Hogan

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

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