

K200908 iSMILEDec 22, 2020
260 days to decisionK200908 · Product code: **NXC** · Dental
Source: <https://www.510kdatabase.net/k200908/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Apr 6, 2020
Decision date	Dec 22, 2020
Days to decision	260 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	3D Diagnostix, Inc.
Location	Allston, MA, US
Contact	Ehab Amin
510(k) history	2 submissions · 2 cleared · 2020-2020

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