

K182658 BiolinerJun 19, 2019
267 days to decisionK182658 · Product code: **NXC** · Dental
Source: <https://www.510kdatabase.net/k182658/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Sep 25, 2018
Decision date	Jun 19, 2019
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Five Star Orthodontic Lab & Supply
Location	Denton, TX, US
Contact	Andrew Loch
510(k) history	1 submissions · 1 cleared · 2019-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182658/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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