

K181747 Orthodontic ApplianceApr 18, 2019
290 days to decisionK181747 · Product code: **NXC** · Dental
Source: <https://www.510kdatabase.net/k181747/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Jul 2, 2018
Decision date	Apr 18, 2019
Days to decision	290 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Shandong Huge Dental Material Corporation
Location	Rizhao City, CN
Contact	Maggie Zheng
510(k) history	8 submissions · 8 cleared · 2016-2026

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