

K193622 TRIOCLEAR SystemJul 6, 2021
558 days to decisionK193622 · Product code: **NXC** · Dental
Source: <https://www.510kdatabase.net/k193622/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Dec 26, 2019
Decision date	Jul 6, 2021
Days to decision	558 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Perfection Aligner System Hong Kong Limited
Location	Kowloon, Hongkong, HK
Contact	Alwin Ngai
510(k) history	1 submissions · 1 cleared · 2021-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193622/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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