

K251758 Serafin®Sep 11, 2025
94 days to decisionK251758 · Product code: **NXC** · Dental
Source: <https://www.510kdatabase.net/k251758/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Jun 9, 2025
Decision date	Sep 11, 2025
Days to decision	94 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tns Co., Ltd.
Location	Geumcheon-Gu, KR
Contact	Byung Ju Kang
510(k) history	2 submissions · 2 cleared · 2024-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251758/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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