

K251616 Clear MiracleJul 22, 2025
56 days to decisionK251616 · Product code: **NXC** · Dental
Source: <https://www.510kdatabase.net/k251616/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	May 27, 2025
Decision date	Jul 22, 2025
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ods Co., Ltd.
Location	Incheon, KR
Contact	Kyung-Ran Back
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	SMB Korea Co.
Contact	Kyung-hwan Kim

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)