

K233544 MESHEETFeb 22, 2024
111 days to decisionK233544 · Product code: **NXC** · Dental
Source: <https://www.510kdatabase.net/k233544/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Nov 3, 2023
Decision date	Feb 22, 2024
Days to decision	111 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dentis Co., Ltd.
Location	Dalseo-Gu, KR
Contact	Gyu Ri Kim
Website	https://www.dentis.co.kr
510(k) history	37 submissions · 37 cleared · 2008-2026

Dentis Co., Ltd. is a Dental device manufacturer based in Dalseo-Gu, South Korea. The company has received FDA 510(k) clearances from total submissions. All submissions focus on Dental devices, with a regulatory history spanning from 2008 to 2026. The company remains active, with recent clearances demonstrating ongoing product development and market engagement. Dentis specializes in dental implant systems, abutments, and associated clinical equipment. Recent cleared devices include implant fixtures, abutment components, scanning and healing systems, and dental chairs, ref...