

K260527 FACE4D Aligner

Jul 2, 2026
135 days to decision

K260527 · Product code: **NXC** · Dental
Source: <https://www.510kdatabase.net/k260527/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Aligner, Sequential (NXC)
Date received	Feb 17, 2026
Decision date	Jul 2, 2026
Days to decision	135 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Avinent Implant System S.L.U.
Location	Santpedor, ES
Contact	Anna Cortina
510(k) history	3 submissions · 3 cleared · 2020-2026