

K220562 TiGEN Abutment, ZrGEN Abutment and Scan Healing AbutmentNov 10, 2022
255 days to decisionK220562 · Product code: **NHA** · Dental
Source: <https://www.510kdatabase.net/k220562/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Feb 28, 2022
Decision date	Nov 10, 2022
Days to decision	255 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Megagen Implant Co., Ltd.
Location	Santa Fe Springs, CA, US
Contact	Hyo-Eun Lee
510(k) history	31 submissions · 31 cleared · 2008-2025

REGULATORY CONSULTANT

Consulting firm	Daegyeong Regulatory Affairs Institute
Contact	Hyo-Eun Lee

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220562/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026