

K210826 Healing Abutment, Cover ScrewFeb 3, 2022
321 days to decisionK210826 · Product code: **NHA** · Dental
Source: <https://www.510kdatabase.net/k210826/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Mar 19, 2021
Decision date	Feb 3, 2022
Days to decision	321 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	You Jung Kim
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

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