

K242287 SFIT AbutmentSep 16, 2025
410 days to decisionK242287 · Product code: **NHA** · Dental
Source: <https://www.510kdatabase.net/k242287/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Aug 2, 2024
Decision date	Sep 16, 2025
Days to decision	410 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cowellmedi Co., Ltd.
Location	Newington, NH, US
Contact	Haejun Lee
510(k) history	14 submissions · 14 cleared · 2004-2025

REGULATORY CONSULTANT

Consulting firm	LK Consulting Group USA, Inc.
Contact	Priscilla Chung

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

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