

K231411 INNO SLA Submerged Hybrid Ti-Base SystemDec 20, 2023
218 days to decisionK231411 · Product code: **NHA** · Dental
Source: <https://www.510kdatabase.net/k231411/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	May 16, 2023
Decision date	Dec 20, 2023
Days to decision	218 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](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231411/> 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 13, 2026