

K201323 INNO SLA Submerged Implant SystemJan 25, 2022
617 days to decisionK201323 · Product code: **NHA** · Dental
Source: <https://www.510kdatabase.net/k201323/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	May 18, 2020
Decision date	Jan 25, 2022
Days to decision	617 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cowellmedi Co., Ltd.
Location	Newington, NH, US
Contact	Minjin Park
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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201323/> 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 25, 2026