FDA 510(k) Premarket Notification

K231411 INNO SLA Submerged Hybrid Ti-Base System

CLEARED

Dec 20, 2023
218 days to decision

K231411 · 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