

K231557 ZENEX FreeMilling & CCM Cast AbutmentAug 24, 2023
86 days to decisionK231557 · Product code: **NHA** · Dental
Source: <https://www.510kdatabase.net/k231557/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	May 30, 2023
Decision date	Aug 24, 2023
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Izenimplant Co., Ltd.
Location	Pyeongtaek-Si, KR
Contact	Ji-Hwan Jeong
510(k) history	8 submissions · 8 cleared · 2022-2026

REGULATORY CONSULTANT

Consulting firm	Withus Group, Inc.
Contact	April Lee

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/k231557/> 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 14, 2026