FDA 510(k) Premarket Notification

K232170 Ti Link Abutment

CLEARED

Jan 12, 2024
175 days to decision

K232170 · Product code: **NHA** · Dental
Source: https://www.510kdatabase.net/k232170/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Jul 21, 2023
Decision date	Jan 12, 2024
Days to decision	175 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Izenimplant Co., Ltd.**
Location	Pyeongtaek-Si, KR
Contact	Mi-Kyung Kwon
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