FDA 510(k) Premarket Notification

K213506 NB 1 SA Implant System

CLEARED

Apr 6, 2022
156 days to decision

K213506 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k213506/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Nov 1, 2021
Decision date	Apr 6, 2022
Days to decision	156 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Arum Dentistry Co., Ltd.**
Location	Yuseong-Gu, Daejeon, KR
Contact	Hyang Mi Lee
510(k) history	17 submissions · 17 cleared · 2020-2025

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