FDA 510(k) Premarket Notification

K210161 AnyOne Onestage Implant System

CLEARED

Jun 22, 2021
152 days to decision

K210161 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k210161/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Jan 21, 2021
Decision date	Jun 22, 2021
Days to decision	152 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Megagen Implant Co., Ltd.**
Location	Santa Fe Springs, CA, US
Contact	You Jung Kim
510(k) history	31 submissions · 31 cleared · 2008-2025

REGULATORY CONSULTANT

Consulting firm	**Daegyeong Regulatory Affairs Institute**
Contact	You Jung Kim

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov