FDA 510(k) Premarket Notification

K223339 Bone Chamber Implant

CLEARED

Jul 18, 2023
259 days to decision

K223339 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k223339/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Nov 1, 2022
Decision date	Jul 18, 2023
Days to decision	259 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	Eun Mi Park
510(k) history	31 submissions · 31 cleared · 2008-2025