

K223339 Bone Chamber ImplantJul 18, 2023
259 days to decisionK223339 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223339/> 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 13, 2026