

K213599 SuperLineFeb 23, 2022
100 days to decisionK213599 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k213599/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Nov 15, 2021
Decision date	Feb 23, 2022
Days to decision	100 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dentium Co., Ltd.
Location	Dunwoody, GA, US
Contact	Eunsang Lee
510(k) history	22 submissions · 22 cleared · 2004-2022

REGULATORY CONSULTANT

Consulting firm	PaxMed International, LLC
Contact	Kevin A Thomas

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213599/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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