

K243066 Dental Implants and AbutmentsDec 16, 2024
80 days to decisionK243066 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k243066/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Sep 27, 2024
Decision date	Dec 16, 2024
Days to decision	80 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ditron Dental, Ltd.
Location	Ashkelon, IL
Contact	Ariel Zuhovitzky
510(k) history	2 submissions · 2 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	Talmed , Ltd.
Contact	Shifra Hoch

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/k243066/> 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