

K221847 Ni2 Implant SystemApr 11, 2024
657 days to decisionK221847 · Product code: **DZE** · Dental
Source: <https://www.510kdatabase.net/k221847/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Jun 24, 2022
Decision date	Apr 11, 2024
Days to decision	657 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Newton Implant Systems, Inc.
Location	San Diego, CA, US
Contact	Pedro Yang
510(k) history	2 submissions · 2 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	Provision Consulting Group, Inc.
Contact	Joyce Kwon

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221847/> 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 14, 2026