FDA 510(k) Premarket Notification

K221866 S-Plant Dental Implant System

CLEARED

Jan 18, 2024
570 days to decision

K221866 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k221866/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Jun 27, 2022
Decision date	Jan 18, 2024
Days to decision	570 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