FDA 510(k) Premarket Notification

K251938 GEN5 and GEN5+ Dental Implant System

CLEARED

Oct 30, 2025
128 days to decision

K251938 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k251938/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Jun 24, 2025
Decision date	Oct 30, 2025
Days to decision	128 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Paragon Implant Mfg., LLC**
Location	Calabasas, CA, US
Contact	Renee Bennett
510(k) history	4 submissions · 4 cleared · 2025-2025