

K252145 GEN5™ and GEN5+™ 3.3mmD Dental ImplantsDec 23, 2025
167 days to decisionK252145 · Product code: **DZE** · DentalSource: <https://www.510kdatabase.net/k252145/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Jul 9, 2025
Decision date	Dec 23, 2025
Days to decision	167 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

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