

**K251938 GEN5 and GEN5+ Dental Implant System**Oct 30, 2025  
128 days to decisionK251938 · Product code: **DZE** · DentalSource: <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	<b>Paragon Implant Mfg., LLC</b>
Location	Calabasas, CA, US
Contact	Renee Bennett
510(k) history	4 submissions · 4 cleared · 2025-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251938/> 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