FDA 510(k) Premarket Notification

K252090 Pterygoid Indication for GM Helix Implants

CLEARED

Dec 12, 2025
163 days to decision

K252090 · Product code: **DZE** · Dental
Source: https://www.510kdatabase.net/k252090/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implant, Endosseous, Root-form (DZE)
Date received	Jul 2, 2025
Decision date	Dec 12, 2025
Days to decision	163 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**JJGC Ind?stria e Com?rcio de Materiais Dent?rios S.A.**
Location	Curitiba, BR
Contact	Mariana Hartmann
510(k) history	10 submissions · 10 cleared · 2021-2026

REGULATORY CONSULTANT

Consulting firm	**Straumann USA, LLC**
Contact	Jennifer Jackson

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