FDA 510(k) Premarket Notification

K251613 SwissGraft X

CLEARED

Jun 26, 2025
30 days to decision

K251613 · Product code: **NPM** · Dental
Source: https://www.510kdatabase.net/k251613/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Bone Grafting Material, Animal Source (NPM)
Date received	May 27, 2025
Decision date	Jun 26, 2025
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Geistlich Pharma AG**
Location	Washington, DC, US
Contact	Erik Wirth
510(k) history	26 submissions · 26 cleared · 2011-2026

REGULATORY CONSULTANT

Consulting firm	**Telos Partners, LLC**
Contact	Roshana Ahmed

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