FDA 510(k) Premarket Notification

K240661 Geistlich Bio-Oss®

CLEARED

Jul 12, 2024
126 days to decision

K240661 · Product code: **NPM** · Dental
Source: https://www.510kdatabase.net/k240661/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Grafting Material, Animal Source (NPM)
Date received	Mar 8, 2024
Decision date	Jul 12, 2024
Days to decision	126 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Geistlich Pharma AG**
Location	Washington, DC, US
Contact	Marco Steiner
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