FDA 510(k) Premarket Notification

CLEARED

K252253 Geistlich Mucograft® /Geistlich Mucograft® Seal

Nov 25, 2025
127 days to decision

K252253 · Product code: **NPL** · Dental
Source: https://www.510kdatabase.net/k252253/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Barrier, Animal Source, Intraoral (NPL)
Date received	Jul 21, 2025
Decision date	Nov 25, 2025
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Geistlich Fibro-Gide®

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	**QUARAS, LLC**
Contact	Roshana Ahmed

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