FDA 510(k) Premarket Notification

K251062 Geistlich Bio-Gide

CLEARED

Aug 14, 2025
132 days to decision

K251062 · Product code: **NPL** · Dental
Source: https://www.510kdatabase.net/k251062/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Barrier, Animal Source, Intraoral (NPL)
Date received	Apr 4, 2025
Decision date	Aug 14, 2025
Days to decision	132 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Geistlich Bio-Gide® Shape; Geistlich Bio-Gide® Compressed; Geistlich Bio-Gide® Forte; Geistlich Bio-Gide® Perio; Geistlich Combi-Kit Collagen®; Geistlich Perio-System Combi Pack

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