

K212463 Geistlich Bio-Gide, Geistlich Bio-Gide Shape, Geistlich Bio-Gide Compressed, Geistlich Bio-Gide Perio, Geistlich Combi-Kit Collagen and Geistlich Perio-System Combi PackApr 5, 2022
242 days to decisionK212463 · Product code: **NPL** · Dental
Source: <https://www.510kdatabase.net/k212463/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Barrier, Animal Source, Intraoral (NPL)
Date received	Aug 6, 2021
Decision date	Apr 5, 2022
Days to decision	242 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](https://accessdata.fda.gov)**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212463/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026