FDA 510(k) Premarket Notification

CLEARED

K192042 Geistlich Bio-Gide, Geistlich Bio-Gide Shape, Geistlich Bio-Gide Compressed, Geistlich Bio-Gide Perio, Geistlich Combi-Kit Collagen, Geistlich Perio-System Combi-Pack, Geistlich Mucograft and Geistlich Mucograft Seal

Aug 29, 2019
29 days to decision

K192042 · Product code: **NPL** · Dental
Source: https://www.510kdatabase.net/k192042/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Barrier, Animal Source, Intraoral (NPL)
Date received	Jul 31, 2019
Decision date	Aug 29, 2019
Days to decision	29 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	27 submissions · 27 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