FDA 510(k) Premarket Notification

K250833 SwissMembrane X

CLEARED

Apr 15, 2025
27 days to decision

K250833 · Product code: **NPL** · Dental
Source: https://www.510kdatabase.net/k250833/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Barrier, Animal Source, Intraoral (NPL)
Date received	Mar 19, 2025
Decision date	Apr 15, 2025
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	SwissMembrane X Socket

APPLICANT

Company	**Geistlich Pharma AG**
Location	Washington, DC, US
Contact	Erik Wirth
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