FDA 510(k) Premarket Notification

CLEARED

K203496 Nexo-Gide Bilayer Collagen Membrane

Jul 14, 2021
229 days to decision

K203496 · Product code: **FTM** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k203496/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical (FTM)
Date received	Nov 27, 2020
Decision date	Jul 14, 2021
Days to decision	229 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	**Biologics Consulting**
Contact	Joshua Crist

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