FDA 510(k) Premarket Notification

CLEARED

K213803 FIBERGRAFT Aeridyan Matrix Bone Graft Substitute

Aug 23, 2022
260 days to decision

K213803 · Product code: **MQV** · Orthopedic
Source: https://www.510kdatabase.net/k213803/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Dec 6, 2021
Decision date	Aug 23, 2022
Days to decision	260 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Prosidyan, Inc.**
Location	Philedelphia, PA, US
Contact	Charanpreet S. Bagga
510(k) history	12 submissions · 12 cleared · 2014-2025

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Janice M. Hogan

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