FDA 510(k) Premarket Notification

K193513 SIGNAFUSE Bioactive Bone Graft

CLEARED

Jun 18, 2020
182 days to decision

K193513 · Product code: **MQV** · Orthopedic
Source: https://www.510kdatabase.net/k193513/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Dec 19, 2019
Decision date	Jun 18, 2020
Days to decision	182 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Bioventus**
Location	Durham, NC, US
Contact	Kim Patterson Kelly
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**Mrc-X, LLC**
Contact	Christine Scifert

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