FDA 510(k) Premarket Notification

K203218 CaP Spheres Pellet Pack

CLEARED

May 4, 2021
183 days to decision

K203218 · Product code: **MQV** · Orthopedic
Source: https://www.510kdatabase.net/k203218/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filler, Bone Void, Calcium Compound (MQV)
Date received	Nov 2, 2020
Decision date	May 4, 2021
Days to decision	183 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Zimmer Biomet Spine, Inc.**
Location	Broomfield, CO, US
Contact	Leo Su
510(k) history	15 submissions · 15 cleared · 2017-2021

REGULATORY CONSULTANT

Consulting firm	**MRC Global, LLC**
Contact	Christine Scifert

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