FDA 510(k) Premarket Notification

K202338 SpaceFlex Shoulder

CLEARED

Feb 17, 2021
184 days to decision

K202338 · Product code: **MBB** · Orthopedic
Source: https://www.510kdatabase.net/k202338/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Cement, Antibiotic (MBB)
Date received	Aug 17, 2020
Decision date	Feb 17, 2021
Days to decision	184 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**G21, S.R.L.**
Location	San Possidonio, IT
Contact	Filippo Foroni
510(k) history	12 submissions · 12 cleared · 2015-2025

REGULATORY CONSULTANT

Consulting firm	**RQMIS, Inc.**
Contact	Barry Sands

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