

K202338 SpaceFlex ShoulderFeb 17, 2021
184 days to decisionK202338 · 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](https://accessdata.fda.gov)

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