

K190216 SpaceFlex KneeJun 9, 2019
125 days to decisionK190216 · Product code: **MBB** · Orthopedic
Source: <https://www.510kdatabase.net/k190216/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Cement, Antibiotic (MBB)
Date received	Feb 4, 2019
Decision date	Jun 9, 2019
Days to decision	125 days
Third-party review	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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190216/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026