

K192449 Joline Kyphoplasty System AllevoMay 27, 2020
264 days to decisionK192449 · Product code: **NDN** · Orthopedic
Source: <https://www.510kdatabase.net/k192449/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cement, Bone, Vertebroplasty (NDN)
Date received	Sep 6, 2019
Decision date	May 27, 2020
Days to decision	264 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Joline GmbH & Co. KG
Location	Hechingen, DE
Contact	Peter Kohlbecher
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	BioVera, Inc.
Contact	Robert A Poggie

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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